

A review of Certificate of Need health care policy programs: At the intersection of science and politics.

Note: this paper has been prepared specifically for the Washington State Health Care Authority and is derived from a longer work written by the author in May of 2003.

I. How to Study CON

It would be accurate to sum up any extensive analysis of the research, reports, writings, reactions, testimony and beliefs about whether Certificate of Need (CON) policies are effective by concluding that it depends on what one wants the answer to be, what one wants CON to do, what one counts as “working”, how one implements and supports a CON program, the practicality of the goals the program is charged with achieving, and so on. For instance, most CON programs have been charged with the Herculean tri-part goal of expanding access to health care, containing health care costs, and improving health care quality but no CON program can has either the authority or resources necessary to accomplish those tasks. Still, much can be learned from studying the 40 or so year history of CON and that study can effectively inform policy makers.

II. Claiming the Mantle of Truth: Empiricism and Argument

In an attempt to add some light to the heat in the ongoing tug of war between the pro-regulation and pro-competition camps in the health care public policy debate, this paper examines the history, impacts, and potential future of CON. One benefit enjoyed by this review is that we now have forty years of CON policy, process, results and reactions to examine. This is counterbalanced, however, in the opinion of this writer, by CON having been particularly victimized by the “what do you want it to be” syndrome. From researchers to policy makers, the history of CON seems characterized by biased support, attacks, evaluation, history, credit and blame.

This author attempts to critically analyze what is known and not known about CON, particularly what is not known but has been claimed to be known. For example, it is this author’s conclusion that many claims that CON has failed to help control rising health care costs and many claims that it has helped to control rising health care costs state more than the research underlying them is competent to conclude. As in a battle of expert trial witnesses loath to admit when they don’t have adequate data upon which to state an opinion, researchers of CON have often offered conclusions even if the data and research methodology were inadequate for the purpose.

III. “What Lies Beneath”: What to Expect in This Review

This paper reviews the history of CON, the market failure aspects of the health care sector, and how CON programs are structured and function in general. It also examines whether CON programs work and what factors, such as loopholes in the laws, lack of common definitions, or independent variables might be affecting outcomes. It also

examines the arguments of pro- and anti-CON parties. The effects of deregulation, impacts of cream skimming, uncompensated care, employers' interests, hospital mergers, health maintenance organization development and decline, and antitrust activity are also considered.

In addition to this largely historical and quantitative approach, this paper reports on interviews with people in several states who are working in state agencies or other organizations that implement or have to comply with CON programs. It also includes a discussion of three CON case studies, in Alabama, Oklahoma, and Illinois.

IV. The Problem: Health Care Costs

Professor Kenneth R. Wing wrote, in 1985 that "The problem, if not critical, is one that at least requires immediate attention and one that will soon require some difficult social and political choices: the need to contain rising health care costs...health care cost inflation continues to dramatically outpace inflation in general; and the aggregate, annual cost of health care has reached extraordinary levels and can be extrapolated to continue to grow at remarkable rates in the coming years."¹

When Professor Wing wrote this, health care expenditures consumed what was considered to be a shockingly large 9% of the gross domestic product. By 2002 that had risen to a 14% bite out of our gross domestic product.²

Utilizing cost of living data from the American Institute for Economic Research, we can calculate that per capita health care spending should have risen from \$141 in 1960 to only \$747.40 in 1996 rather than \$3,781.³ The real increase was more than five times higher than the rate of CPI increase. If other sectors of the economy had grown at this rate, in 1996:

- A \$20,000 car would instead have cost \$101,156.81
- A \$200,000 house would instead have cost \$1,011,568.11
- A \$3 gallon of milk would instead have cost \$15.28
- A \$100 hotel room would instead have cost \$505.90
- A \$35,000 annual income would instead have been \$177,026.43

V. Executive Summary: Do We Know Anything after almost Four Decades of CON?

Surprisingly, even with the complexities of the process, politics and economics of CON and health care marketplaces, some conclusions do emerge from a fair review of the law, history, implementation, and controversy about CON:

1. Neither CON nor competition models appear to have had much impact on the extreme increases in health care costs that have plagued the American economy since at least the 1960s.
2. There is evidence that CON has had some positive effects on hospital capital expenditures, mostly by encouraging more planning, by having a sentinel

effect on growth, and by slowing down some expansion plans and duplication of services.

3. The traditional “market failure” and “public good” characteristics of health care that served as the rationale for regulation still exist:
 - a. the social goal (and legal requirement) of care being provided regardless of ability to pay
 - b. demand largely being determined by the same party that supplies the services
 - c. guaranteed payment for almost all the services providers can provide
 - d. lack of effective competition in many markets, either through natural factors such as geography, regulatory factors such as CON, or predatory market practices such as anti-competitive mergers and other cartel behaviors
 - e. hospitals not competing based on price, but rather competing for the allegiance of doctors by increasing facilities, adding equipment, paying larger salaries, and instituting prestigious programs such as heart surgery
 - f. there is evidence that when hospitals lose business to competition, either other hospitals or ambulatory surgery or diagnostic centers, they do not lower prices. Rather, they raise prices on the other services the hospitals still provide and for which they still have a monopoly in the market
 - g. consumers have little ability to influence whether they need hospital services and generally do not comparison shop for hospital services when they do need hospital services
 - h. most people have third-party reimbursement (either private insurance or government benefits) for their hospital expenses and are generally unaware of, and not responsible for, most of the cost of treatment
 - i. one aspect of the system, the Medicare and Medicaid programs, can mitigate utilization and charges, but is only partially successful because providers are able to cost-shift (charge more than cost plus reasonable profit) to other payers, especially insurance companies
 - j. the primary impact of market failure and public good features is a health care system that can basically be as big as it wants to be and be guaranteed that someone (either government programs or third-party insurance) will pay whatever charges it sets
4. The health care system is dominated by a paradigm that thwarts most attempts at cost control: this paradigm is the guaranteed, third-party payment to providers who influence demand and determine charges, and who have few incentives for price or cost competition.
5. One of the dominant conflicts in modern healthcare, particularly concerning hospitals, is between established hospitals trying to maintain monopoly power and entities such as ambulatory surgery centers that are trying to enter the market.
6. Two ideological schools, one labeled “pro-regulation” and one labeled “pro-competition” are locked in conflict over the future of health care, and

virtually all health care policy issues, concepts, and proposals tend to be pre-judged based on which of these ideological camps the policy makers, researchers, professionals, or consumers identify with.

7. Neither an increased and more effective regulatory system nor a well-functioning competitive system are likely to occur in the foreseeable future. The former would require substantial control over providers and the latter would require destruction of current programs of guaranteed third-party payment, consumer protection, guaranteed issue, and equity mandates.
8. Realistically, the alternatives are:
 - A. accept the current paradigm: that health care will continue to consume larger and larger shares of the gross domestic product and of state and federal budgets (already 20-25% of state budgets);
 - B. make incremental progress, “bend the curve”: making modest adjustments to regulations, encouraging more consumer involvement in health care decision-making about services and benefits, encouraging providers to be more efficient, encouraging healthy lifestyles and disease management programs, trying to change reimbursement mechanisms to pay providers more for prevention efforts and less for acute care, working to support continued financial health of insurance plans;
 - C. experiment in several states with new funding and delivery models such as single-payer, mandated-insurance, reduced regulation, or new methods of introducing competition;
 - D. replace the blank check health care financing system with a defined bank balance: find a mechanism to either set providers’ rates (as is done with utilities, taxicabs and others) or create annual budgets for providers and give them the freedom and responsibility to manage within those budgets. A growing portion of the health care payer sector – Medicare and Medicaid - already sets a global budget. If the private sector budget could do likewise, for instance through a law that caps third- party payments at 105% of the Medicare rate, providers such as hospitals would know what their budget is and have both the obligation and the freedom to manage to the budget. Beyond setting of the global budget, decision-making would be at the provider level where, presumably, they would know best how to allocate finite resources.

VI. How We Got Here: an Introduction to CON

(A). A Brief History

Although it seems health care cost containment has been an issue forever, it really was a non-issue in America until the advent of Medicare in 1965, with the federal government then becoming a significant third party payer.⁴ The government’s major role in health care prior to that was through the Hill-Burton Act, as the federal government encouraged spending on new health care equipment and construction and modernization of facilities.

Particularly because of the deal the government struck with doctors to get Medicare adopted, guaranteeing to pay “usual and customary” charges, increased cost pressures were inevitable.

Adding to the impact of guaranteed third party payment of usual and customary charges was the so-called “Roemer Effect” – the principle that a bed built is a bed filled. In other words, supply in the health care world pushes demand, largely because providers play the dominant role in determining what services consumers need. The idea of requiring certain providers, particularly hospitals, to obtain a Certificate of Need (CON) before undertaking capital expenditures was seen as the “most effective way to control utilization and third party expense [by controlling or reducing] supply.”⁵

Our current CON regulatory schemes are largely derivative of the one developed in the National Health Planning and Resources Development Act of 1974. “While considering the new federal health planning law, Congress found that the major weaknesses of the forerunner Comprehensive Health Planning (CHP) Program were that CHP agencies were seriously underfunded, understaffed, uncertain as to their direction, and lacking in authority to make substantial changes in the health care system.”⁶ Many of the inherent problems of the original CHP law afflicted the CON law, however, and other problems arose. These included provider domination (knowledge, resources, credibility, interest), staff domination, conflicts of interest, and review criteria and standards that are very elusive and difficult to use effectively.⁷

As with many public policy initiatives, CON was first launched at the state level, with New York implementing the first CON program in 1964.⁸ CON was at first generally supported by the health care industry.⁹ Today, as will be discussed in great detail below, the industry is split over the notion of CON, with existing providers – especially well established ones - generally supporting it and those seeking entry into or expansion within the market generally opposing it and arguing for more competition in the health care marketplace.

Between 1965 and 1977, prior to the federal government’s involvement in CON, thirty-six states, the District of Columbia, and Puerto Rico adopted CON laws. Significant assumptions about the health care marketplace underlay the enactment of these laws:

- Capital costs in health care are passed on to consumers
- Competition in health care does not lead to decreased charges because providers control supply and also determine much of the demand, and because consumers lack information
- Consumers don’t shop around for health care, at least not based on price
- Increased costs lead to increased charges
- Consumers don’t pay most of the cost and don’t really know the true cost of, and charges for, care.
- Providers have no direct incentives to lower charges or utilization¹⁰

(B). Whether CON works

It seems the dominant question about CON has always been “does it work?” This will be discussed in greater detail below, but it is essential to also address it in this brief description of the history of CON because notions of whether CON works or not have driven much of its history. Two fundamental, perhaps dispositive, problems have historically plagued state CON programs:

1. good health planning results in analytically sound but often unpopular restrictions on health systems growth
2. such planning has often resulted in political influence over what was conceived as a primarily analytic process¹¹

States were required to develop, with substantial local input, a state health plan and local health systems plans, to define the need for certain types of health facilities and services. The plans were based in large part on socioeconomic models defining needs in terms of so many hospital beds, so many CT scanners, etc. per 1,000 or 100,000 population. The law was unclear, however, as to ex parte communications (contact with decision-makers outside of the actual decision-making process and off the record). Ex parte “gradually became the norm, resulting in widespread disregard of the analytically derived health plans.”¹² Where does public input end and improper political influence and ex parte communication begin? The history of CON seems to indicate the states have done a poor job addressing this issue.

The answer to whether CON works is also complicated by many factors, not the least of which are conflicting methods of evaluation, conflicting definitions of what having it “work” means, and conflicting goals that are expected from CON. For instance, in order to determine if it works, one could look at the number of CON applications denied, reasoning that if X applications for Y millions of dollars are denied there is a tangible savings in health care dollars that can be credited to the CON program. But what if, especially some years after the CON program has been in place, some applications for capital expenditure are not even submitted because the providers expect they will be denied? This would make good business sense, saving the expense of going through a process one expects would not be successful. The health care dollars saved by the decision of a provider to not apply for a CON would not, however, be counted by the typical researcher who simply looks at the number of applications submitted, number of applications denied, and so forth.

Furthermore, as providers learn what is likely to be approved and what is not, and as CON guidelines and policies are developed, indicating what the capital spending priorities are in a state, one would expect applications that suit the guidelines to dominate the total number of applications submitted. Consequently, one would see the percentages of applications approved to increase rather than decrease. This could lead some researchers to opine, as we will see below, that CON doesn’t work because an overwhelming percentage of applications get approved. This conclusion ignores,

however, the fact that the existence of CON might have significantly changed what projects are applied for and how they are constituted.

In part, we are talking about things such as what some people call the “sentinel effect” of CON - stopping capital projects before they become CON applications. Others note that measuring the success or failure of CON should not just look to the dollar amount of proposed projects approved and denied, but also to the long- term operating costs that flow out of capital projects undertaken. Typically, researchers assessing the savings achieved by CON have only added up the capital construction dollars or medical equipment dollars identified in the application. This ignores the fact that a new wing of a hospital will likely mean more staff members, supplies, utility costs, indirect costs, and so forth, to run it. Likewise, CON opponents sometimes complain that proponents’ claims of health care dollars saved through CON ignore the costs involved in participating in and complying with the CON process.

(C). Problems Right from the Start

By 1980 all states were required by federal law to have CON programs¹³ but major problems immediately appeared. First, the kickoff of this national mandate coincided with the start of a presidential term of office marked by antagonism to the notion of government regulation. The Reagan administration was vigorously opposed to the regulation of industries ranging from transportation to health care. Also, implementation of the CON ideal quickly revealed many problems. Among these were:

- 1) difficulties filling statutory gaps: how to treat leases, personnel costs, grants, donations, transfers, mergers, etc. when determining jurisdiction over health care facility capital expenditures, the splitting up of projects, and the phasing in of projects over two or more years in order to avoid jurisdictional triggers,
- 2) providing enough due process but not so much that delay cost more money than would be saved by good policy decisions,
- 3) determining who would make CON decisions (appointed boards, state agencies, governors, etc.), and
- 4) problems defining the criteria to be applied, in particular the problem of determining the definition of “need” for health care projects.¹⁴

Perhaps the overarching difficulty with CON programs arose from the stated goals:

“Most CON programs, including the federal one, have one stated goal: ***the promotion of equal access to quality health care at reasonable cost.*** The problem is that this single, seemingly unimpeachable goal is in reality three goals that compete and are often mutually irreconcilable: quality, accessibility, and cost control.”¹⁵ (emphasis added)

(D). Need: a scientific or political concept, or both?

The centerpiece of CON is the determination by some decision-maker, charged with pursuing cost control, access and quality, that the project rises to the level of being needed, not just wanted. Payers might see need as fundamentally rooted in cost control, as a means to make project proponents prove a system failure will result without the proposed expenditure being undertaken. Providers, on the other hand, might see need as being about quality: they need to undertake the expenditure in order to maintain or improve quality. Consumers might see accessibility as the major goal and might also easily be oriented toward quality by the arguments of providers. Contrary to a “let’s control costs” goal, providers and consumers could easily see need as meaning more and better facilities.

Regulators should see CON as having one essential purpose: to keep costs down. Indeed, when CON was initiated some regulators thought its purpose was to set the stage for a pending national health care solution that would solve the cost problem systemically.¹⁶ The primary problem to be addressed by the federal CON legislation was rapidly increasing health care costs, not lack of quality or serious access problems. Health care costs were not only rising, but they were rising 6% per year higher than the rate of inflation. It was believed that the possible approaches to control costs were to 1) rejuvenate the market, 2) require components of the system to operate on fixed annual budgets, perhaps by region, or 3) enact direct regulation, perhaps as public utilities are regulated.¹⁷

(E). CON as Planning and Process

The federal CON policy was notable for how laden it was with planning and review, not just the approval process.¹⁸ All of the state laws enacted, except for Oklahoma’s, included need certification for new hospital construction, and most covered facility construction, addition of bed capacity and physical plant expansion in nursing homes. Many addressed significant expansion of services and expenditures on equipment, and about half covered freestanding outpatient facilities. All of the CON laws exempted individual doctors’ offices. Several required CON approval of major cutbacks in services as well as expansion because cutbacks could affect service delivery, other institutions’ CON applications or plans, or regional and state planning.¹⁹

Clark Havighurst noted that nonprofits’ behavior is not that different from for-profits. They too seek growth as a primary source of managerial gratification: “Nonprofit hospitals sometimes ‘distribute’ profits in the form of perquisites to – or lucrative business contracts with enterprises controlled by – trustees, managers, or controlling physicians.”²⁰ It has also been shown that “under the demand conditions of a seller’s market, hospitals’ costs tend to rise so that their prices seem to behave not too differently from those of for-profit firms.”²¹ This behavior is not necessarily a bad thing. As Havighurst noted:

“If the excess earnings of nonprofit hospitals are used to supply more or better services and are not wasted in overpayments or invested improperly, there is no

reason to object to them, on distributive grounds, as monopoly profits and perhaps no reason to condemn cartel practices which produce them.”²²

“Even though cartels have been outlawed in other industries, special considerations, such as the impact of third-party payment and the prevalence of nonprofit firms, might dictate dispensation for cartel-like behavior in the hospital industry.”²³

VII. Case Study #1: Oral Roberts City of Faith

It all came to him, evangelist Oral Roberts said in the late 1970's, in an extraordinarily detailed vision from God. He was to construct the City of Faith – a \$250 million medical complex including research and diagnostic buildings and a 777 bed hospital, all adjacent to his Oral Roberts University in Tulsa, Oklahoma. Tulsa County, however, had ten underused and financially pressed hospitals that reported a total of 1,000 empty beds daily. The Oklahoma Health Systems Agency turned down Roberts' request to certify yet another hospital.

Roberts then contacted his world-wide mailing list, and half a million letters of support swamped the state capital. Roberts' lawyers argued that it was these followers, rather than citizens of Tulsa, who would fill up the hospital. The three members of the state's Health Planning Commission were inundated with 310,000 pieces of mail and over 3,000 phone calls. Both houses of the Oklahoma legislature passed resolutions urging the commission to approve the application. Testimony was presented at the commission that 506,000 donors had given more than \$27 million for the project. The Tulsa County Medical Society was polled about the project, however, and 78% of those voting opposed the project (488 of the 645 members, or 76% of the membership, voted) and said there was no need for it. The commission voted unanimously to allow Roberts to go ahead with a 294 bed hospital and add the rest of the 777 beds later. Opponents vowed to appeal, but “within two hours of the vote the hospital's first foundation pillar was being set.”²⁴

The hospital rose 60 stories tall above Tulsa and was completed in 1981. Oral Roberts said it cost \$250 million but was opened debt free.²⁵ In 1989, with most beds never filled, Roberts closed the hospital saying that God told him to close it. The Medical School also closed. The Medical Research Center, planned to be 21 stories tall, only had 3 stories developed by 1984.²⁶ The hospital operated in the red for all but two months of its existence.²⁷

Both proponents and opponents of CON-type planning could point to this case as evidence in support of their arguments. Proponents could argue that had the CON process been characterized by more science (judge the need for the hospital on the facts) and less politics (giving in to pressure from the legislature, hundreds of thousands of letters and thousands of phone calls), the hospital would not have been built and many resources would not have been unwisely spent. Opponents could argue that a scientific CON process devoid of excessive political influences has never been developed and this case illustrates that vividly. Perhaps, they would argue, it would have been better to avoid

spending time and money trying to evaluate such projects and just let them succeed or fail of their own doing.

CON supporters might also argue that applicants not as determined as the Reverend Roberts might be more open to listening to others' input in the CON review process and decide not to go ahead with projects that are too risky. For instance, another project proponent might have heeded the warnings from the other area hospitals that there was insufficient demand to provide the business needed to meet the greatly expanded hospital bed capacity in Tulsa. Opponents could also point to this case as an example of how poorly regulatory schemes can turn out despite looking good in the theoretical and developmental stages. Consider Bovbjerg's advice in 1978 about how to improve CON process – advice that, not unlike Professor Havighurst's advice – did not survive the legislative and administrative machinations that are the policy making process. Bovbjerg recommended the following steps to improve CON:

- compare methods for meeting a perceived need
- ensure that lower cost alternatives are identified in order for comparisons to be made
- have competitive reviews through a batching process²⁸ As an example, the Federal Communications Commission holds competitive proceedings to allocate a limited number of broadcast station licenses²⁹
- engage in more planning in order to do it well and so as not to just be reactive³⁰
- develop and maintain an independent viewpoint skeptical of providers' claims of need³¹
- ensure good staff work emphasizing the importance of cost controls and the need to demonstrate positive results for the population served³²
- ensure the staff can provide a contrary point of view to the applicant³³:
“Applicants can be relied upon to underline the strengths, as they see them, of their proposals; as a counter, staff should focus on weaknesses and should develop an independent point of view. In fact, resources, permitting a designated staff member should probably oppose all applications; a devil's advocate role is useful even when decisions may seem obvious.” Such advocacy should highlight issues and help reviewers work toward independent standards on a case-by-case basis.”³⁴
- have non-applicant presentations such as are provided through the Massachusetts “ten-taxpayer” groups³⁵ (any group of ten taxpayers may demand party status to intervene in an application)
- have secret balloting by the decision making body to prevent providers from profiling commission members and lobbying them over time
- reviewers should be skeptical. Make applicants prove improved health of the population served – a “show me” attitude. Reviewers should “strive to make applicants show need in social terms – results for patients and populations – rather than in terms of medical process or institutional needs.”³⁶
- make comparisons between providers as a proxy for quantitative standards

- don't use an approach that assumes a CON should be granted unless the staff can prove otherwise. The burden of proof needs to be on the applicant.³⁷

Bovbjerg advised that "...planners and certificate of need reviewers must be prepared to be somewhat arbitrary in putting downward pressure on prevailing patterns of practice, both in setting quantitative standards in advance and in reviewing particular projects for certification of need."³⁸

The history of CON regulation has been of regulation that has not, for the most part, risen to the standards Bovbjerg or Havighurst advised were necessary to make it work. The applicants are required to carry the burden of proof and in some jurisdictions there are quantitative standards to guide some decision-making. By and large, however, the statutes, regulations and procedures that have resulted do not contain a critical mass of the "required elements", if you will, that these authors and others have prescribed to make the system effective for the purposes to which it has been designed.

VIII. Market Failure and The Rationales for CON

Professor Clark Havighurst's 1973 article in the Virginia Law Review remains a monumentally insightful and important work about the theory and practice of CON programs. He was not particularly optimistic or supportive about the science or potential effectiveness of CON programs, noting that CON laws "attempt to deal merely with symptoms rather than root causes."³⁹

In 2001, Laurretta Higgins Wolfson restated the unique market failure characteristics of our health care industry, showing, as others have, that nothing has improved since Havighurst's key writings in the 1970s. According to Wolfson (no fan of CON, as is illustrated later in her account of the Heart Hospital controversy in Illinois), there is a need for regulation in health care because:

- institutional health care facilities are economically induced to manipulate or increase supply by over-investing in technology, beds and services without regard to actual need or demand.
- increased supply encourages increased demand which, in turn, leads to increased costs⁴⁰

Wolfson invites us to compare the market dynamics in health care to those in the typical grocery store as an example of the extreme market failure present in health care. In the grocery store:

- the store supplies goods in relation to demand.
- if the store increases prices, the consumer chooses to pay it, do without or shop elsewhere

But in health care:

- there is little competition
- there is a scarcity of price information for consumers

- the average patient is not equipped to make decisions about costs, supply and demand of health care
- patients lack knowledge about health care needs and services, rely on doctors to tell them what they need and what it should cost
- “Unchecked providers and uninformed consumers create demand which leads to unwarranted and irresponsible supply.”
- costs are generally paid by third party payers which then pass costs along indirectly by allocating costs to and among all insureds. This insulates patients from concern regarding direct payment for services.⁴¹

Some believe that the evidence is not sufficient, however, to conclude that unchecked supply creates unwarranted demand. Judge Richard Posner, for example, notes that although prices should be higher in markets with fewer hospitals they typically are not. He ignores other factors, however, that can keep health care monopolies from acting like monopolies and exploiting their monopoly power as much as they can. Many, for instance, are non-profits whose missions and cultures mitigate against fuller exploitation of their monopoly power.⁴²

(A). Why Market Failure is Critical in Health Care:
It Means a Failure to Allocate Resources

We have yet to construct a process theory in this country for dealing with claims within health care issues:

“Under the present system (or non-system), individual patient and provider complaints raising issues about access to treatment, the quality of care and the cost of health services are adjudicated in a bewildering legal matrix of forums and procedures.”⁴³

In a free market system, most allocative decisions are “made invisibly by participants in capital markets who seek to maximize their profits and preferences by directing resources to their most valued use, including health care.”⁴⁴ In health care, we must also make allocative decisions’ about who will receive the resources we have. CON is one attempt to deal with the market’s failure to deal with allocation of health care resources.

Writing in the Journal of Law and Health, Margaret G. Farrell notes that “Individuals in a market system cannot claim a legal right to health care they cannot afford.”⁴⁵ In our market failure health care system, however, it is very different, with many distributive claims to health care being made:

- a right to treatment regardless of ability to pay
- subsidies (from cost-shifting to supports for medical colleges, research and more)
- opposition to all but nominal co-payments and deductibles
- coverage types and conditions mandated by law
- mandated portability
- anti-discrimination laws
- determinations by third parties, including government, as to medical necessity

- guaranteed coverage and benefits for the poor and elderly
- claims to particular levels of quality
- mandated care regardless of ability to pay

Contrary to the three common models for determining distributive questions – negotiation, collaboration, and adversarial proceedings,⁴⁶ in health care a “rights” paradigm dominates absent many tools to make allocative decisions. The result is our health care cost crisis. While the crisis continues and reforms elude us many employers have curtailed employee benefits and related costs, increased deductibles, shifted other costs to employees, and negotiated directly with providers for lower charges.⁴⁷

One writer noted that his local Health System Agency’s board of trustees set 99 percent as the confidence level for having an acute care bed available when needed. He claimed that in private business, however, this would be the equivalent to carrying extremely high inventories to meet an extraordinary standard of 99 percent customer service levels. He advocated “strong local pressures to control needless expenditures from the businesses and employees who pay the bill and from consumers who pay for it in the form of product prices.” He raises a very interesting, rarely articulated viewpoint: that we do, in effect have a universal health care financing system because most people are paying for it through taxes (to support Medicare and Medicaid) and product prices (to support the cost of employer-provided health care benefits). Of course, this misses the UN-universal aspect of this system - the benefit received by employers who do not choose to provide health insurance as an employee benefit. They are arguably at a competitive advantage and not part of a funding system for health care benefits, except perhaps to the extent their employees qualify for tax-funded health care.⁴⁸

The lack of customary market controls on excess spending is illustrated by Dr. Ted Cook’s remarks about diagnostic services: “Most of us feel 95 percent of the time we don’t need the MRI to help us with a proper diagnosis.”⁴⁹ Critics say hospitals buy these services out of a desire for status and that once they have them they must use them to protect themselves from malpractice, regardless of need. Some hospitals are using mobile MRIs to solve the price problem while others are using mobile ones because they don’t require a CON – a means of getting around the law.⁵⁰

Former Oregon Governor and State Senate President John Kitzhaber asked “can the state control costs without some variation on the Certification of Need program to regulate the supply of expensive, high-tech equipment and services?” He believes there “needs to be a way to regulate not only redundant acquisitions but also their use...It’s arguable whether the Certificate of Need process worked...I don’t think we can just get rid of it without having something to replace it.”⁵¹ Noting that states don’t have the option of deficit spending (in fact, one state, Vermont, can legally deficit spend but does not) as the federal government does, Kitzhaber claims states must solve health care spending crises each year. Usually that means dropping people from Medicaid programs or cutting their program benefits in hard times.

Kitzhaber makes a profound argument that interest group liberalism, as he understands it to have been described by political scientist Theodore Lowi, is partly to blame. According to Kitzhaber, “the rise of government regulation and independent bureaucracies turned the process of policymaking away from the pursuit of the common good – however imaginary that might be – and toward a divying up of the spoils by politicians and interest groups.”⁵² This could explain, in part, our difficulty solving the health care cost and access crises: stakeholders are battling to preserve their market shares, benefits, limited contributions, control over demand and pricing, and so forth.

(B). Political Market Failure: Politicians Don’t Do “Take Away”

“In 1971, Senator Edward Kennedy and his aides wrote a book about the world of American medical care entitled *In Critical Condition: The Crisis in America’s Health Care*.”⁵³ Reflecting on that book, Theodore Marmor, writing in 1986, claimed:

“The sense of trouble typified by this book was so widespread that both Republicans and Democrats, liberals and conservatives, competed over which form of national health insurance to enact. In 1974, for instance, the now forgotten Kennedy-Mills proposal received extended consideration in the finance committees of the Congress, as did the Nixon CHIP plan and the catastrophic health insurance bill of Senators Long and Ribicoff.”⁵⁴

The Carter administration proposed health care cost controls in 1977 but they were defeated by opposition from hospitals, distrust of the Carter team, and doubts that the plan would work. Small hospital chains grew into large companies and “Both Democrats and Republicans had been influenced by a generation of academic policy analysts (mostly economists) who ridiculed the regulatory costliness and the captured quality of decisions of the independent regulatory agencies in Washington.”⁵⁵

So, when President Ronald Reagan came into office the stage was set for competition and de-regulation in health care. One irony, however, is that the biggest health care initiative of the Reagan period, Medicare’s prospective payment system of diagnostic related groups (DRGs), is a sophisticated, highly regulatory form of price control that changes the incentives facing hospitals. Ideology aside, this move was absolutely necessary to stem what would have been a much worse escalation of health care costs had the “usual and customary” reimbursement standard continued to apply in Medicare.

Theodor Marmor claims “the reality of health politics in the 1980s” was one of incremental steps of both a regulatory and competitive variety, what he reported having been called “agitated incrementalism.”⁵⁶ Rather than the public being motivated to do something about the aggregated rising costs of health care, individuals were only concerned with the cost of their own premiums and other forms of cost-sharing.”⁵⁷ DRGs introduced another element of market failure, the substantial shifting of costs to other payers.

Perhaps the key reason Congress does not focus much energy on solving the cost crisis, according to Marmor, is that health has become a “take away” area – “not exactly an ideal foundation for building a political career.”⁵⁸ There are many oxen to potentially get gored when treading into the health care funding policy arena. For example, employer contributions to fund medical benefits are not taxed. In 1990, that lost tax revenue equaled \$35.6 billion. In theory, this money could be used for a program of direct expenditures for health services.⁵⁹ Coincidentally, NBC Nightly News reported, on February 10th, 2003, that it costs \$35 billion a year to care for the uninsured currently through emergency room care. Hospitals note that such care is much more costly than other, more predictable and manageable kinds of care.

In addition, there is also the likelihood of a disconnect between some policy decisions Congress imposes and the personal experiences of members of Congress. For instance, they have championed the use of HMOs but Marmor reported that, at least as of 1985, not one member of Congress was in an HMO, nor was anyone in the top leadership levels at the White House.⁶⁰

Professor Kenneth Wing’s research points up some factors that also would give policy makers pause when considering health care reform:

- most Americans like what they have in health care
- we like freedom of choice
- we think quality is very high and don’t want to gamble with it
- providers do very well financially, as do the people and institutions that finance and manage health care, and are not likely to give that up. They are very influential in Washington, state government, corporate boardrooms, etc. They finance political campaigns and the uninsured do not.
- opponents of health care reform are very good at tapping into the “freedom of choice” theme

He noted that “Even the recurring reminders of things we do not like about health care – rising costs, the plight of the uninsured, the inequitable results for some people – are not enough to overcome our political inertia, not to mention the political influence of those forces that are working hard to reinforce our immobility... When it comes to health care, our views are ambiguous, loosely defined and, often contradictory.”⁶¹

He also notes that politicians “wisely stop short of giving us details about plans to fix health care” and instead “tell us stories of health care denied and managed care that does not manage or care.” They rarely try to educate us as to realistic alternatives or to organize us politically.⁶²

(C). “If you build it, they will come.”

It has been approximately four decades since Milton Roemer’s observation about the utilization-increasing effects of excess health care facility capacity, the so-called Roemer Effect. It was a driving force behind the institution of CON programs. “A bed built is a bed filled,” was the saying that captured the spirit of this law of health care utilization.

But, even if the Roemer Effect was true then, does it still apply? A lot has changed since the '60s, including Medicare's prospective payment system, the development of HMO's, and capitated payment systems just to name a few.

Factors such as the expanding prevalence of third-party payment for the cost of treatment seem to be giving the Roemer Effect a very long life indeed. Francesco Taroni, writing in 2001, observed that:

“Since insurance coverage and third party reimbursement for the full cost of treatment eliminate the opportunities for price competition, competition for patients and their physicians must be primarily based upon the scope and quality of the services offered.

“Several studies provide empirical evidence of extensive duplication of services and redundant hospital capacity in competitive markets. When cost-reimbursement policies provide easy financing of the associated cost, competition drives capacity up, because hospitals develop a full range of services to attract and retain medical staff and patients.

Taroni seems to have moved on from CON regulation as the solution, however, advocating “[r]ate setting programmes, putting hospitals at financial risk for the cost of their services, [as]...a regulatory strategy to curb hospital expansion that might be more feasible and as effective as imposing external approval.”⁶³

In June of 2000, the Finger Lakes Health Systems Agency, based in Rochester, New York, published a study entitled “Capacity Matters.” In its report, the agency provides a strong argument that Roemer's Effect is alive and well, at least in the Rochester area. The group concluded that there is substantial evidence that excess capacity leads to increased costs, under-utilized facilities and increased use of health care services.⁶⁴ The study also found that excess capacity and utilization may also:

- jeopardize quality of care
- lead to heightened competition and loss of cooperation among providers
- result in a loss of medical management to non-physician reviewers
- lead to loss of community control

As evidence of excess capacity in the Rochester area, the study noted declining rates of hospital occupancy, the substitution of ambulatory services and the conversion of hospital beds to other uses. Despite decreasing occupancy, however, “hospitals continued during the 1990s to renovate and in some instances build new facilities largely of the same size.” For instance, the study noted that despite a 50 percent occupancy rate in Rochester obstetric units, all of the area obstetric units were redeveloped in the 1990s at a cost of approximately \$50 million and at about 80 percent of their previous size.⁶⁵ Of course, the hospitals might correctly claim that they were responding to the lower occupancy rates by reducing the size of the units and that they were responding to what their consumers wanted by modernizing the obstetrical units. The hospitals should also be able to make a

valid argument that all capital facilities must be replaced over time and that a well run facility should be modernizing its units in timely cycles of plant replacement.

The study points the finger at physicians, noting that the Rochester area has a large number of physicians – 287 per 100,000 population as compared to 109 per 100,000 people for the greater Finger Lakes region. Another reason cited is doctors' opposition to hospital privileges and insurance reimbursement for mid-level practitioners.⁶⁶

The Rochester report cited the following effects of excess capacity in the Rochester area and other places around the country:

- the establishment of a new ambulatory care facility in town at the same time there is considerable vacancy at the hospital means the hospital will increase prices even if it can reduce staff and close operating rooms because it has to pay fixed costs.
- "In state after state, as [CON] programs were repealed, a major expansion of service capacity occurred. In Phoenix, Arizona, for instance, five new cardiac catheterization programs, which had previously been rejected by the CON program based on lack of community need, were initiated within the first year after repeal of CON controls; volume at each program was well below optimum... Bryce and Cline demonstrate that in the six years following repeal of CON in Pennsylvania, lithotripter supply doubled, procedure volume per machine fell from 773 to 489, against a capacity of 1,000 to 2,000 per machine. Average operating cost per procedure in 1994 was estimated to be \$2,107, but would have been only \$1,331 if each machine were performing 1,000 procedures."⁶⁷ Also, Pennsylvania's MRI capacity more than doubled and volume per machine dropped to between 60 and 75 % of state guidelines. Cardiac catheterization lab capacity increased 90% and the average volume fell from 1,034 to 758 per lab. By contrast, in the Rochester area at that time average volume was 1,750 per machine.

The study indicated that where excess capacity exists, evidence suggests physicians use more medical procedures. This is the "capacity generates utilization" described in the 1960s by physician and health care researcher Milton Roemer. He saw that communities with a greater supply of beds tended to use hospital services at a greater rate. Dr. Jack Wennberg has shown that Roemer's Law still holds even in the age of the prospective payment system. Similar patterns have been shown with the supply of doctors and of high-tech equipment.⁶⁸

The Rochester study also reviewed the modern concern that excess capacity can negatively affect the quality of care: "If a specialist does too few cases, quality deteriorates."⁶⁹ This view, being voiced by providers and researchers, expresses the importance of practitioners performing enough high skill procedures to attain and maintain proficiency. Bryce and Cline reported, for instance, that 15% of Pennsylvania catheterization labs do not meet minimum volume standards. The American College of Obstetrics and Gynecology, the March of Dimes Foundation, and the Federal government

have concluded that quality of care improves with increasing obstetrical unit size and with a minimum standard of 50 births per year.

An October, 2002 report in the Journal of the American Medical Association indicated that risk adjusted mortality was 22% higher in the 18 states that had no CON regulation for open heart surgery than in the 26 states (and D.C.) that had continuous CON regulations. The higher mortality was observed in all six years of the study.⁷⁰

Excess capacity also fosters unproductive competition for doctors and business.⁷¹ The Rochester study cites the example of every hospital in the Rochester area developing new obstetric units that resulted in excess obstetric capacity.⁷²

At the same time, the study claimed that there is substantial under-investment in prevention services, information technologies, and dealing with shortages of nurses and other health personnel.

The study claims that “Milton Roemer’s proposition that ‘a built bed is a filled bed’ is one of the few accepted generalisations (sic) about hospital performance. Over 40 years and across different health care systems, consistent empirical findings confirm Roemer’s observations: if more beds are available, more will be used; since supply induces demand of hospital services, effective control of hospital use must rely primarily on some external regulation of bed numbers.”⁷³ The authors indicate that the elasticity of increased use is found to hover around 53%, i.e., a 10% increase in the number of beds will produce a 5.3% increase in bed days.⁷⁴

(D). Third party payment and facilities duplication

Cost shifting and the inefficiencies that result from the fact that payment is guaranteed, either from government or private insurance, for utilization of services that hospitals and doctors can tell patients they need, creates significant market failure and increases costs. Havighurst noted that because of negotiations between hospitals and insurers for reimbursement formulae, third-party payments frequently include some of the costs of other services, meaning the public rather than the hospitals absorb the costs of excess capacity.⁷⁵ Also, “under this payment system, the public pays the full cost of all occupied and many unoccupied hospital beds and of many unremunerative or underutilized services, either through taxation, in the case of public programs, or through health insurance premiums.”⁷⁶

Insurers and the government might be able to prevent excess capacity were it not for the control hospitals can exercise over their own occupancy. According to Havighurst, “By letting it be known that higher occupancy is desired, the hospital can usually cause a loosening of institutional utilization review and can encourage doctors both to opt for hospitalization in close cases and to prolong their patients’ stays.”⁷⁷

Much of the subsequent research about CON seems to have downplayed this very crucial component of market failure in the health care systems, particularly hospitals. As will be

discussed later, these later researchers tend to promote a pro-competition argument and a central pillar of their argument is that the health care system can be more efficient and cost effective by the introduction of competition because other industries, from fast food to automobiles, do so. The utilization-increasing and cost-increasing impacts of third party payment are largely ignored, however, in these analyses.

One need not do extensive modeling, regression analyses or longitudinal studies to grasp the simple logic at play in third party payment such as in our health care system. An analogy I like to use to illustrate the problem concerns my peers, lawyers. Suppose 85% or so of all men, women and children in the United States – and all the lawyers – knew that either the government or an insurance company was obligated to pay for all the legal services lawyers prescribe for people. What would likely happen to the cost and quantity of legal services performed? How many more lawsuits, divorces, wills, contracts, and legal challenges to affronts large and small would be spawned?

Indeed, how much more expensive might the computer systems, stenography machines, expert witnesses, and even legal pads that the legal system uses become? Before Medicare and Medicaid, and before employer-provided medical insurance, health care was rationed by the financial means of the patient. There was a market constraint on what suppliers could charge and how expensive the system could become: the ability and willingness of the buyers to buy.

Unlike legal services, however, we decided in the latter half of the 20th century that broad access to comprehensive and high quality health care was a social good. With this social good, and the third party payment mechanisms used to implement it, came the unintended but predictable consequence of skyrocketing costs and increased utilization. What can counter these consequences? Havighurst notes that competition in the health care sector has not, at least during the third party payment era, been waged around price, but rather on wooing and pleasing doctors (the key-holders to utilization).

CON is based on the theory that regulation is needed to curb the proliferation and duplication of facilities and equipment used by hospitals as tools to convince doctors and patients that certain hospitals are the ones the doctors and patients should patronize - not because the hospitals have lower prices or are more efficient, but because they have the latest and greatest of everything, and more of it than anyone else.

(E). Decision Making in Hospitals: Incentives in Nonprofit Enterprises

Havighurst also examined the incentive environment of hospitals, explaining that “Such institutions are excessively concerned with institutional size and prestige – reflected in the quantity and technical sophistication of the care rendered – and the concomitant material and other benefits accruing to their managers, trustees, or sponsors.”⁷⁸ Thus, the market is generally unable “to induce nonprofit hospitals to close down beds or to go out of business altogether once they have been replaced by more efficient or better located facilities.”⁷⁹ People are simply “unlikely to vote themselves out

of jobs or prestigious positions as long as they can meet the payroll, even at the expense of recoverable capital.”

Randall Bovbjerg, writing just a few years after Havighurst (1978) considered the thesis that medical practice dominates the concept of need, that alternatives such as giving weight to social valuations are poorly developed, and that it was doubtful health planners’ methodologies could prevail over health professionals’ ideology.⁸⁰ He noted that these peculiarities of the market for institutional health services encourage overinvestment:

- dominance by non-profits which have diminished incentive to control costs
- an “edifice complex” of non-profit organizations: “large, new, well-equipped facilities add to institutional prestige and administrative status.” It also boosts local pride and attracts doctors.
- tax status encourages philanthropy
- government policy, such as Hill-Burton, encourages capacity building
- there is a lack of price competition – people don’t have cheaper hospitals to choose from.⁸¹
- there is a lack of “refuse to use” pressure on demand. The sick can’t really decide to stay home because of the expense.⁸²
- third party payers have been either unwilling or unable to induce hospital cost control by minimizing the price paid
- “Lenders are more concerned with the availability of third-party revenues than with a demonstration that the proposed facilities or equipment are needed.”
- hospitalization decisions are largely made by doctors, not patients
- means by which hospitals compete for patronage of doctors leads to overinvestment – doctors prefer well-equipped, modern and uncrowded facilities.⁸³

Bovbjerg concluded that “all these incentives point in the direction of overinvestment and higher costs” and that the “costs are not borne by the institutions or communities responsible for them, but rather by much larger groups through insurance premiums and taxes.” In addition, he noted that hospitals have reason to put pressure on doctors to increase utilization to pay for the facilities. Doctors paid on a fee for service basis have little reason to restrain utilization.

(F) The Role of Doctors

According to Havighurst, “Competition among hospitals for doctors also explains a great deal of duplicative investment, perhaps not in beds so much as in exotic equipment which duplicates underused facilities at nearby institutions.” He claimed that hospitals compete more actively for doctors than for patients, since doctors have more to say than patients about hospital use. And, since doctors don’t pay for the use of the hospital and usually have no reason for concern about patients’ bills, competing hospitals seek to provide services and facilities which make the doctors’ practices more lucrative, with the costs being paid by third-party payers.

(G). Quality of Care and Economies of Scale

Speaking to another issue that would be used decades later to justify retaining CON programs, Havighurst opined that “Where a surgical team performs an operation only rarely, its success rate may be significantly lower than it should be”⁸⁴ and that maintaining multiple facilities may spread and underutilize the available talent. CON, on the other hand may help realize economies of scale.

(H). Cream Skimming

Another unusual and important component of how our hospitals operate in the marketplace involves the practice of cream-skimming. Quite simply, hospitals have few profitable cost centers and many unprofitable ones. For instance, the emergency department of a hospital is a money loser. It is expensive to operate because of many factors including the high caliber of staff required, the unpredictability of use, the need to be open 24 hours a day every day of the year, and the need for expensive equipment and supplies. Also, a disproportionate share of the patients who use the emergency department are poor and uninsured or on Medicaid or Medicare. These patients either cannot pay anything for their care or they will pay, through the government programs, a price that is usually less than the hospitals’ costs for delivering that care. Open-heart surgery, on the other hand, is an example of hospital services that a hospital makes a profit on. Indeed, most surgeries are profitable. Hence, when freestanding, ambulatory operating facilities seek to enter a hospital’s market area, the hospital will usually be extremely concerned that the competition will deprive the hospital of revenues essential to support the programs within the hospital that lose money.

There are really two aspects to this type of activity that hospitals often refer to as cream-skimming. The newcomer to the market may both deprive the hospital of some of its most profitable business *and* take the particular parts of that business that are the least costly to serve. For example, a 2002 CON case in Vermont produced evidence that the largest owner of ambulatory surgery centers in the country, HealthSouth, not only takes away some of a local hospital’s surgery when HealthSouth opens up a facility in town, but it also takes the surgery cases that are the least costly to perform and that yield the most profit.⁸⁵ So, the hospital is left with fewer, more expensive and less profitable patients to treat.

If the existing hospital is providing a lot of indigent care, it has a particularly strong interest in preventing competition from facilities that will not have to carry the extensive fixed costs the hospital must.

As Havighurst observed the scene thirty years ago, he believed the cream skimming argument had “less merit in the long run” because “a national health insurance program for the poor may have obviated the social necessity for financing indigent care in this manner.”⁸⁶ Little did Havighurst and others know that the problems with cost shifting and lack of a national health insurance program were to grow worse rather than better.

IX. How CON Laws Operate

The basic, who, what, when, where and how of CON processes have changed little since the 70s. Although they vary from state to state and have been through many reform iterations over the years, they are characterized by the following basics of due process:

- jurisdictional thresholds,
- a written application process,
- review by some department of government,
- consideration by state officials and/or public boards,
- review based on the application of criteria, guidelines, regulations, and so forth,
- standards of proof, and
- appeal rights.

Some states now “batch” CON application so as to require that applications for like projects be submitted and reviewed at the same time of the year. This responds to criticism from some facilities that feel they have a poorer chance of winning approval if they happen to apply after other facilities have applied for similar projects. Some regulators favor batching for another reason, that of enabling the regulators to get a better feel for what is happening in the aggregate in health care facility construction in a state. Rather than approve a huge project in one town today and then be surprised to get an application for a similar project in the same town or a nearby town very soon thereafter, regulators might be able to engage in better planning and long range thinking if they were able to see all similar plans for similar institutions at the same time. This might also give rise to discussions about collaboration between facilities.

Of course, the law of unintended consequences is vigilant. In some states where batching is used, it results in multiple applications for the same project pending at the same time. This happens because facilities that file court appeals about denials of their CON applications file repeat CON applications while the appeals are pending to guard against missing a subsequent batching cycle if they lose their case on appeal.

(A). Who are the decision makers?

This can be difficult to identify. Sometimes a state agency head, such as a commissioner of health, may be charged by statute with making CON decisions. Sometimes that commissioner is charged with considering recommendations from a public body, such as a CON advisory commission. Some such bodies have final say. Typically, however, Havighurst found such decisions are advisory⁸⁷ and frequently, the decisions are “sketchy and unrevealing” and lack any explanation of the dissenters’ views and rationales.⁸⁸ Decades later, this is still often the case.

(B). Hearings, appeals and decisions

Formal opposition to CON applications is rare but those whose market position is threatened may file competing applications. Usually, the competing claim is that the existing facility can meet all the need. The lack of formal opposition to applications can create a very advantageous situation for applicants. Over the years they can get to interact frequently with their regulators, developing relationships and establishing trust. This can easily lead to varying degrees of agency capture, in which the regulator and regulatee are more colleagues than adversaries.

One area in which Havighurst saw this play itself out was in the loosely defined yet critical CON criteria concerning need for the proposed project. Because CON programs have usually given little guidance as to how to determine whether a proposed project is needed, this creates opportunities for “political influence, favoritism, and misguided policies...” according to Havighurst. He argued that “...no major regulatory program at the federal level...has escaped criticism that the policies pursued usually advance the interests of the regulated industry itself.”⁸⁹ In the world of CON regulation, there is often no definition of need or guidance as to what it means. Doctors may believe a new machine is needed because it is “state of the art” and will be better than the old machine. Regulators might rather want to apply a “use it up, wear it out, make it do, or do without” theory of need. Local community members excited by the potential for new jobs and taxes coming into the community might have a much lower threshold for whether a new program, service, piece of equipment or facility is needed.

CON statutes also vary widely as to standing required to be an interested party and to appeal decisions. In some states only unsuccessful applicants are permitted to appeal. But this means one can’t appeal a successful application that leads to overcapacity.

(C). Criteria for Assessing Need

As mentioned, CON criteria have traditionally been spelled out in statute but have often been so conflicting, numerous and vague so as to allow the decision maker great flexibility. This can be quite the two-edged sword, both enabling skilled regulators to act in the common good but also causing applicants great difficulty because it is hard for them to know ahead of time what the standards are that they will be held to.

Key among CON criteria is the issue of need. At first blush a straightforward concept, whether the facility, service, program or equipment is needed, evidence clearly suggests this has been the Achilles heel of CON programs. The early drafters of CON as a cost control concept failed to specify any definition of need or, indeed, give any clear guidance as to what need should mean. Havighurst found that determining need is “so exceedingly complex that, unless the decision maker spells out its policies in advance, the vague criteria of most state programs permit the agency to function with little effective oversight by judicial or other authorities.”⁹⁰

Randall Bovbjerg’s work illustrated well how the issue of need in CON cases has been measured as a medical concept defined by providers rather than as an analytical concept determined by planners, elected officials and citizens. As Bovbjerg warned:

“Need is a medical concept, largely defined by professionals. It is subjective, rather than objective, and consequently is not a limiting, but an expansive concept...medical need reflects what professionals deem desirable, rather than what patients can afford. Professionals decide what is needed according to their concept of what constitutes good care, which tends to be established according to the state of the art-what is medically possible at a given time. Virtually any medical benefit is seen as a need; medical professionals are generally guided by a more-is-better philosophy, which has been characterized as a ‘technological’ or a ‘quality imperative.’ This approach is in keeping with the preferred professional role of seeking the best possible services for those being cared for. Thus, when we as individuals want to know what medical intervention is needed, we ask our doctors.”⁹¹

“But, where what is deemed medically desirable cannot be paid for, the resulting shortfalls in care or facilities are apt to be considered evidence of ‘unmet’ needs, rather than appropriate compromises made in allocating limited resources.”⁹²

“But, under the current system of almost open-ended third party reimbursement, resources have been easily available and inpatient investments have grown remarkably. Medical notions of “need” have not operated as a restraint. To the contrary, as one commentator has noted, ‘The quality, quantity and style of medical care are indefinitely expansible. The medical care system can legitimately absorb every dollar society will make available to it.’”⁹³

“...there is virtually no limit to the amount of medical care an individual is capable of absorbing.” Quoting J. Enoch Powell, former Minister of Health, Great Britain.⁹⁴

The Planning Act embodies a philosophy that rational planning can define need by developing and applying technical expertise. The central process is the development of objective, numeric standards to rationalize health facilities and determine the correct investments to be made.⁹⁵ According to Bovbjerg, “The very word ‘planning’ has a comfortable aura of expertise, suggesting precise computations, scientific methodology, and rationality” as opposed to aggregating individual needs as determined by individual providers.⁹⁶ There is little agreement, however, on what constitutes health and less on how it can or should be measured.

We also know little about the “production function” of health care – how and to what extent health care services and facilities actually contribute to health. As Bovbjerg observed, “The relation between a population’s use of health care and its health is thus unclear.”⁹⁷ Subjective judgments about the value of costs and benefits “permeate the process” and it “is not politically acceptable for public agencies to engage in ...cost benefit valuations as a central part of their mission.”⁹⁸

Bovbjerg argued that ways must be found to introduce cost as a factor into “insufficiently constrained health care investment decisions.”⁹⁹ One option is a population based method. It introduces the notion of a fixed pie from which all needs must be met – something otherwise lacking in health care need assessments. It promotes decision-making on an “either-or” basis, “forcing choices between competing uses of limited resources, rather than “yes-no” choices of whether an individual resource use is somehow sufficiently needed in the abstract.” He noted that it is very difficult for planners to say ‘no’ to any individual proposal for expansion backed by the professional ideology of need: “Since financial resources have not been limited, there is no counterweight to professional claims of improved health care.” Under an “either-or” system, it’s about saying “yes, but...” instead of saying “no.”¹⁰⁰

While health care providers have relatively clear ideas of what they want, “backed by professional standards for the needs of good practice and by a patient-oriented, more-is-better ideology of need that has been legitimized by long practice¹⁰¹ ...there are no objective standards of need that planners can apply to restructure the system.”

Bovbjerg suggested the following seemingly objective guides to determining need:

- projections from past experience. But this perpetuates past practice patterns, including perhaps inappropriate growth. The appropriateness of current utilization is not challenged.
- look to discern average practice and deviations from it. Again, it accepts current practice as appropriate “despite the fundamental premise ...that current practice is inherently biased toward undesired expansion.”¹⁰²
- direct reliance on professional norms.
- performance of prepaid health care services (HMOs). Example, Kaiser Foundation medical plans “provide good care with only 1.5 hospital beds per thousand enrollees, far below the national average.”¹⁰³ (National average 4.4)

Bovbjerg concluded that the “best counterweight to professional claims on review would be a limited budget and strict “either-or” decision making, but these do not now exist.”¹⁰⁴

X. Case Study # 2: HealthSouth

In existence for barely less than twenty years (as of 2002), HealthSouth grew from a five employee company to be the leading international owner and operator of ambulatory surgery centers and physical rehabilitation facilities, employing over 58,000 people by 2002. Its influence in its home city of Birmingham and its home state of Alabama was substantial. A statue of the company’s founder and former Chief Executive Officer was prominently displayed in Birmingham. Buildings, parks, and even one highway in the area were named after Scrushy.

In 2002, HealthSouth wanted to build a state of the art, \$240 million “digital” hospital. It would replace a 169 bed hospital HealthSouth owned in Birmingham. But Alabama had a fairly rigorous CON law and other hospitals in and around Birmingham opposed the

project. Rather than go through the CON process, HealthSouth convinced the Alabama legislature to completely exempt the project from CON law. CON has existed in Alabama for 17 years and this was the first exemption by legislation.

Not-for-profit Baptist Health Systems and Brookwood Health Services (owned by Tenet Healthcare) sued to block the project, although it was already under construction. They claimed the exemption law was not public noticed as required by law prior to enactment. HealthSouth threatened that without a CON waiver it would build the hospital in another state rather than put up with the CON process in Alabama that HealthSouth claimed would delay the project for six years. A trial, expected to take two years to start, would be too late to stop the project. By that time the hospital would already be built and operating.¹⁰⁵

The plaintiffs in the suit against HealthSouth also claimed it misled Alabama lawmakers in order to obtain tax breaks and the regulatory exemption, including an estimated \$30 million tax break over 10 years from the city of Birmingham. HealthSouth's claims that this would be a unique "digital" hospital were also challenged, with opponents claiming it would really not be any different from computerization other hospitals had.¹⁰⁶

In support of the opponents' claim the "digital" hospital was a sham, Baptist Health Systems notes that it launched a two year, \$25-\$50 million technological upgrade to its ten-hospital system, teaming up with Siemens Medical Solutions Health Services Corp. to install the Soarian clinical software system. "It's a massive upgrade," said Baptist senior vice president and chief information officer Charles Jones. "We're totally replacing the infrastructure throughout our system." He claimed it was the same system HealthSouth was using in its new "digital" hospital.¹⁰⁷

The Alabama Hospital Association also sided with the Birmingham hospitals that sued the state for giving HealthSouth Corp. a regulatory break on the proposed "digital" hospital." The AHA claimed the "exemption is unfair to other hospitals and defeats the state's attempt to contain health care costs through the certificate of need, or CON, process." HealthSouth claimed it deserved the exemption because it was building a "state-of-the-art, completely computerized hospital that will provide economic development for the state."¹⁰⁸ One could argue, however, that if that claim was true HealthSouth should have been able to prove its case in the CON process and get approval.

X. Behavioral Hypotheses Based on Other Industry Regulation

Particularly illuminating among Havighurst's work was his description of the different ways in which regulators and the regulated may behave. With the benefit now of over three decades of CON regulatory behavior it is revealing to look back at the behaviors Havighurst presented and see what has indeed transpired. First, let's review the models of regulatory behavior:

(A). Producer-Protection Hypothesis

In this model, the regulatory agency is “captured” by the industry through “politically inspired appointments, lucrative employment prospects in industry for cooperative regulators, industry’s better opportunity to urge its point of view, its ability to outspend the agency, and its influence with the elected officials who control the agency’s appropriations and legislative charter.”

(B). Prisoner of the Hospital Industry

Even in the absence of actual capture of the bureaucracy by industry, boards such as part-time community boards or agencies may be sympathetic to hospitals’ goals and needs, sharing enthusiasm for more and better health care services. This behavior has been significant in the history of CON particularly because of the lack of any objective, scientific or empirical definitions of need. Into that vacuum quickly entered the doctors who, as highly regarded experts, were effective in convincing lay people that what the doctors wanted was indeed needed. Add to that the usual interest in having everything that is good in one’s community, and the interest in adding jobs, tax revenue and so forth to a community, and it is easy to see how cost control is hard to achieve.

(C). Tool of an Industry Cartel

Regulatory agencies tend to adopt strategies “disturbingly similar to those which an industry-wide cartel or monopoly would pursue if it could.” Prices are frequently kept well above competitive levels, price discrimination is facilitated, and both industry and regulators agree that capacity needs to be limited. Consumers have a hard time opposing a united front of regulator and industry, especially if it looks like duplication and overcapacity are avoided by the regulation.¹⁰⁹

(D). Friend of Industry Insiders

Agencies sometimes become subject to undue political influence on behalf of private interests by legislators and the executive branch.¹¹⁰ The line between getting community input (good community planning) and being lobbied by political interests is a fine one.

(E). Facilitator of Industry’s Good Works

Linked to this feeling of good will is the hospital’s argument that it is a major provider of valuable charity care and needs to be protected, including with the help of regulators, from competition that would harm the hospital’s charitable mission.¹¹¹

(F). The Taxation-by-Regulation Hypothesis

Judge Richard Posner espouses a theory that regulation is a “mechanism of public finance whereby a franchised firm is permitted in effect to impose an excise tax on some of its services on the condition that it apply the excess revenues to providing certain other services, thought to be needed by the public, at less than their cost.”¹¹²

According to Posner, rather than appropriate tax monies, the legislature delegates the power to tax and spend for public purposes to the agency and the agency re-delegates to private or non-profit interests. Posner calls this “taxation by regulation.” When this happens, it not only hides the taxation that is really afoot, but also results in the regulatory agency having a vested interest in maintaining the monopoly entity so as to maintain the agency’s function. To provide universal health care to our citizens, we increase our reliance on hospitals’ charity care, which charity care they trumpet as a reason regulators must protect them from competition from entities such as ambulatory surgery centers.

According to Havighurst:

“Although all regulated industries have demonstrated allocative inefficiencies, particularly with respect to industry size vis-a-vis the rest of the economy, none of them has offered a potential for growth approaching that of the health care industry. Even without internal subsidies protected by regulatory restrictions, belief in health care as an end in itself, the unlimited commitment to ever-improving quality and accessibility, the continuing scientific and technological explosion, and the further weakening of cost constraints through expanded third-party payment together add up to a considerable potential bill. But when this sum is multiplied by the hidden and virtually inexhaustable revenue source, the planners’ enthusiasm for many hospital-based services, and the ever-present necessity for log-rolling in response to numerous clamoring interest groups, the prospect for further inflation in health care costs is staggering.”¹¹³

(G). The Brushfire-Wars Hypothesis

Another behavior of regulatory agencies that Havighurst discusses is that of the agencies getting caught up in fighting brushfires rather than accomplishing meaningful planning.¹¹⁴ Havighurst described this “fighting brushfires” type of regulation as follows:

“Absorbed in deciding inconsequential issues of equity such as which of several applications shall provide a given service, the agencies are unable to perform the socially more important job of prescribing the industry’s structure, determining which services should be offered, and deciding how needed change can be promoted.”¹¹⁵

The reason most frequently offered for lack of planning, according to Havighurst, is lack of agency resources. Also, the issues to be dealt with in planning are often difficult, controversial and intractable.¹¹⁶

Reflecting on Theodore J. Lowi’s diagnosis of the shortcomings of ‘interest-group liberalism’, Havighurst claimed that “True to their political orientation, regulators have defined their functions as that of mediating among interest groups rather than defining the public interest objectively and forcing the regulated firms to accept it.”¹¹⁷

He held out some hope for agency planning, claiming “It may not be inevitable that [CON agencies] will succumb completely to a nonplanning, highly political approach. Health planning does have a methodology for predicting health facility needs and for evaluating arrangements for meeting them...this methodology could perhaps lend credibility to hard decisions and reduce the impact of political pressures and the equitable claims of established providers.”¹¹⁸ He noted it is very complex, however, and requires consideration of these relevant factors:

- “...types, sizes, age, condition, and distribution of facilities; use patterns, including service areas within hospitals; population characteristics and size; availability and accessibility of services and facilities; supply of physicians and other health personnel; income levels; levels of medical technology in the community; health insurance coverage; climate; and the habits of people.”¹¹⁹
- a need to include projecting changes in population, technology, health care financing, delivery systems, and patterns of utilization.¹²⁰
- the degree to which agencies lack faith in their ability to make hard-and-fast judgments, lack firm standards, and succumb to the pressures of politics necessarily becoming dominant.¹²¹

(H). Innovation and Change

If regulation can be done well, avoiding or countering some of the behaviors described above, Havighurst warned that it is a well-supported complaint about regulation that it retards desirable changes and resists the weeding out of obsolete systems. Perhaps monopolistic hospitals, protected by CON laws, are among the best examples of this.

One reason hospital regulation retards innovation and change is an obsession with sunk costs that the industry says it needs to cover. Also, the industry will always be stronger and apply more pressure than any other pressure the agency feels. Havighurst claimed that hospitals permitted their budgets to “become grossly inflated during a period of excess demand and ready cost reimbursement” presenting opportunities for cream-skimming proprietary hospitals, HMOs, and other ambulatory substitutes to offer more efficient, cheaper services.¹²² Those large hospitals are then in a position to exert considerable influence on the regulators, putting forth appealing arguments about protecting charity care and other resources highly regarded by the community.¹²³

XI. Special notes on the Behavior of Certificate of Need Agencies

The history of CON indicates strong support for the following conclusions regarding the behavior of regulators’:

- They have been captured by the industry, as illustrated by an extremely high approval percentage for CON applications, the diminishing vigor of CON

agencies over time, and interpretations of the concept of need that are dominated by industry standards and desires.

- Being faced with legislators who vacillated between embracing theories of regulation and competition, regulators have acted primarily in a defensive mode rather than an assertive, pro-active mode. They have also capitulated to accommodating the dilution of their cost-control functions and goals, taking on the additional goals of improving health care quality and access.
- In recent years, as regulators' interests in preserving CON have coincided with the interests of well-established health care providers to maintain monopoly power, they have been on the same side arguing against those who challenge CON as ineffective as a tool of cost control and harmful to the potential benefits of increased competition in the health care marketplace. Not only have the regulators been captured by the industry, they now rely on the support of the dominant players in the industry in order to remain in business.

Mirroring a widely held view of the 1960s and 1970s, Havighurst believed future HMO development to be the "most promising nonregulatory strategy for bringing the excessive use of health care resources under effective control."¹²⁴ And, he called for some sort of rate regulation, "preferably a system of incentive reimbursement"¹²⁵ for example by grouping hospitals and reimbursing them based on an amount adequate to cover costs at the average hospital in the group. Proving perhaps that there is no such thing as a new idea, this latter incentive concept is currently a hot topic among some hospital management professionals.

Havighurst called for health care planning, even if a jurisdiction does not use CON. If CON is to be done in a jurisdiction, he recommended the following modifications. Interestingly, many of these recommendations are now being debated as reform ideas, perhaps with no recognition that Havighurst or anyone else proposed them decades ago:

- limit provider influence in the process. CON decisions should be made by an agency "which bears direct political responsibility for the cost of health care as a purchaser of care under Medicaid and state employee health programs."¹²⁶ Note that in Tennessee CON reforms placed the state's Medicaid director in a key decision making position regarding CONs and also appointed two other key state fiscal officials to the decision making board.
- limit CON to hospitals and exempt HMOs
- have a very open process and require detailed findings of fact and full statements of reasons and dissenting views as to particular decisions
- mandate reliance on real planning
- if departing from published plans, do so to reflect express commitments to increasing consumer choice, strengthening competition, reducing costs, and encouraging innovation.
- the need requirement should not shelter non-cost related pricing or prevent entry by providers providing less comprehensive care except where care of indigents would unavoidably be jeopardized.

- the law should be sunsetted so as to serve as a moratorium, not permanent regulation.¹²⁷

Havighurst's conclusion in 1973 is sobering to read thirty years later:

“ It is still too early to make the ultimate health policy choice between health planning-cum-regulation and a more market-oriented system which relies primarily on decentralized decisions by providers, consumers and insurers. Both have their adherents in the policy debate, and neither has proved itself as yet, although the imperfections of the market as we know it have been much ventilated. Perhaps in five years it will be possible to assess with greater assurance the impact of such changes as an improved system of national health insurance, HMO development, utilization controls, and various regulatory experiments.”¹²⁸

XII. A Word from The CON Agencies

Thirty-six states and the District of Columbia still have CON regulation. The best source for comparative statistical information is probably the national directory published annually by the American Health Planning Association.¹²⁹ It includes everything from contact information for state CON agencies to comparisons of the various thresholds and types of services regulated. AHPS produces data indicating CON review thresholds, fees, and scope of coverage by state. The Maryland Health Care Commission has also produced a state-by-state CON comparison chart.

Generally, CON states regulate capital expenditures, equipment, or new services costing more than prescribed dollar thresholds. Typical thresholds for capital expenditure range from \$1 million to \$2 million. Equipment thresholds tend to vary more from state to state, with the lower end being around \$400,00 and the upper end being around \$1.5 million. Thresholds for new services are not generally pegged to dollar amounts.

As illustrated by the articles and stories discussed above, it seems that CON regulation is a sure bet to be actively debated in at least a few states every year. The current issues concern the tug between regulation and competition, the tightening or loosening of regulation, and whether CON works –as cost containment, quality control, or both.

In preparation of this paper, a qualitative survey element was added by interviewing randomly selected CON administrators around the country (twelve in total) to get a feel for the lived experience of CON.¹³⁰ Except for one in-person interview, these contacts were all by phone and/or e-mail. I was guided in my discussions by a script but encouraged the respondents to talk with me as they thought best to give me a feel for what is happening in CON regulation in their states. Respondents in a couple of states would not discuss much on the grounds that they were in the middle of CON reform battles in their states and everything was basically too unsettled at the moment. The questions focused on the following:

- The extent of CON penetration in the state
- Current level of CON activity and CON's viability as a regulatory scheme
- Awareness of useful current research about CON
- General history and development of CON in each state
- What CON's future looks like in their state
- What CON research is needed in their state
- What's happening with health care costs in their state
- Key demographic characteristics relevant to health care costs
- Relevant political backdrop
- Relevant backdrop in the hospital sector, insurance sector, employer sector
- Whether the CON program works? What does "work" mean?

Some brief descriptions of these conversations can be instructive as to what's happening "on the ground:"

- ◆ State A: CON penetration is moderate; CON provides a sentinel effect on new projects; the business community is behind it; health insurance premium increases are high (25-41%); the history has been a patchwork of fits and starts, legislative updates, provider-driven changes to CON; a need for more scientific criteria; need for a new state health plan; Medicaid cost crisis is severe; fifth oldest population in the country; politically divided legislature; lots of conflict between the needs of the inner city hospitals and the rural ones; serious tort reform issues on the table; unions and business coalitions are strong and they support CON.
- ◆ State B: believes its system is different than other CON states because they have "taken the politics out" of CON and focus on whether the applicant has the qualifications to run a high quality health care service; banned ex parte communications; the CON application process is a "legal process" rather than a "counseling session"; criminal penalties for each violation lasting for 7 days, fines also; believes big business is spurring renewed interest in CON; there is one decision-maker although councils make recommendations; the agency is run in a very "no-nonsense" way but very "customer service focused"; totally focused on how good the data provided by the applicant is and "making sure that persons/organizations who provide health care are competent to do so."
- ◆ State C: extensive jurisdiction that applies to parent companies of health care facilities as well; deals with termination of programs also, not just new programs; the criteria have been made shorter and simpler; assessments are tied to budgets; has police-like investigative powers; tied to hospital rate approvals which the state also handles; has waivers for equipment replacement; has a law against shifting costs to uninsured persons.
- ◆ State D: heavily involved in surveying facilities and developing mathematical criteria for need; broad public participation in state health plan development; extensive jurisdiction over facilities and types of services; substantial fines for violations (\$5,000 per day); requires charity care commitments; favors regionalization of

services; invites alternative health care models; imaging equipment must meet utilization targets to get approved; extensive definitions of services.

- ◆ State E: CON has primarily kept access available in a rural environment; has had a sentinel effect delaying projects and discouraging every hospital from having everything; the program needs new blood; given small staff, covering too many things jurisdictionally.
- ◆ State F: CON law lapsed and new services rushed in; government dealt with it by focusing on public health issues and disease management, looking at the root causes of utilization such as smoking, diet and lack of exercise; increased quality monitoring; some hospitals would like CON to return but the legislature doesn't seem interested; cost increases are now blamed on nursing shortage and malpractice insurance crisis; tobacco settlement money is being used as a stop gap to help hospitals in need get equipment (65% of tobacco money spent on high tech imaging equipment which some now say is oversupplied).
- ◆ State G: light penetration, decreasing steadily since the mid 1990s, constant attempts in legislature to end CON except for long-term care; very interested in research comparing CON and non-CON states, feels there is a real lack in this area; open-heart is the big topic now; hospitals, nursing homes and hospices want very much to keep CON; substantive debate lacking, just regulation vs. market talk; drug costs and Medicaid costs are center stage politically; term limits have seriously depleted institutional knowledge of CON at the legislature; many legislators are gung ho for competition but change their minds when they focus on preserving their local hospitals; fear of boutique hospitals.
- ◆ State H: biggest battles in recent years have been between hospitals and ambulatory surgery center proponents – this has given CON a big profile in the public; CON has a prophylactic effect; new groups of legislators get interested in getting rid of CON but then get scared by health care costs, especially Medicaid, and leave it alone; has only one community with competition between hospitals; gets a very high Medicare reimbursement rate; aging population; high alcohol and drug use, accidents, trauma; health care ranks below education, budget balancing and other issues.
- ◆ State I: lots of task forces and such debating what to do with CON; it makes the hospitals plan better and propose what will be worthwhile; staff gets asked by legislators to show proof it works and can't; focuses on quality of care and access (regionalized access) a lot; hospitals want to keep it; one large tertiary care hospital skews all the numbers.

These themes seemed to emerged from the interviews:

- CON is not breaking new ground but is fairly entrenched in most states surveyed
- Hospitals are among the strongest supporters of CON

- Legislators and other stakeholders are conflicted by multiple goals
- Most states are engaged at some level in debates about what to do about health care costs but there is a lack of ideas that can command consensus or break through the regulation-competition ideological divide
- Research is lacking and support of or opposition to CON is based largely on anecdotal and emotional information

XIII. Mergers and Antitrust

In the 1990s, one key dynamic of market failure in the hospital sector of the health care industry was the anti-competitive behavior of hospital mergers and hospital purchases of physician practices. This is often cited as the primary reason for the failure of managed care to succeed in containing the rate of increase in health care costs. For instance, there were too many hospitals in Philadelphia.¹³¹ To gain market share, health systems began buying physician practices. This launched a “feeding frenzy” and forced some hospitals to move defensively so they wouldn’t be left out in the cold. According to Steven Altschuler, M.D. President and CEO of Children’s Hospital of Philadelphia, the buying spree ran up everyone’s debt, from which most are still recovering. In 1999, Philadelphia hospitals were leveraging 62% long term debt compared to 38% nationally.

Writing only five years ago, James F. Blumstein examined the market failure aspects in the health care industry. Reflecting on what he sees as a growing challenge to a medical professional paradigm that maintains that the market cannot work in the health care industry,¹³² partly because of the asymmetry of information between providers and consumers,¹³³ he notes that CON laws are “intended to establish a review process by which the proliferation of health care facilities may be controlled”.¹³⁴ He sees the need to use other tools, such as antitrust law, as a potential accommodating factor between the normative, professional paradigm and an empirical paradigm based more on market rules.

Blumstein claims that from the early 1980s through the late 1990s the normative premise has been challenged, that patients were seeking more input, and that there were wide utilization patterns among doctors (citing the 1996 Dartmouth Atlas which “demonstrated wide divergence in patterns of utilization in different regions, without any ostensible scientific rationale.”). He also noted that the introduction of the DRG based reimbursement system for Medicare significantly affected hospital lengths of stay, with a dramatic shift from inpatient to outpatient services. Managed care also produced changes in practice patterns during this time-frame. So, Blumstein concluded, health care can respond to some market mechanisms.¹³⁵

Commenting on Blumstein’s 1998 article, John C. Render claimed that the financial behavior of health care providers can be changed positively by regulation:

“The enactment of the Medicare prospective payment system for hospitals in 1983 and the expansion of Medicare coverage for such services as renal dialysis, home health care and others are merely the most noteworthy illustrations that the

behavior of health care providers, and consumers, will radically change if money is withheld, as in the former example, or is provided as in the latter instances.”¹³⁶

Render notes that the health care field must be distinguished from most other commodities and services because it provides a vital human service. He further notes that “[m]ost other vital human services such as water and power are subject to state oversight in the form of public utility commissions or similar entities. This is based, at least in part, on the notion that such services are so significant that determining their availability by market forces is contrary to civilized values and should therefore not be subject to the varieties of the market system.”¹³⁷

Render states that several important issues and facts should be considered in determining the proper role of the market in the delivery of health care, including:

- (1) “Health care is an area in which the public has considerable experience and perceived knowledge. This may make it more difficult to make policy decisions based largely on empirical data ... For example, duplication of services and equipment by health care providers is not always seen by the consuming public as being pro-competitive nor positive... Such duplication ... may not result in better quality or lower prices.”
- (2) “Health care markets can be very imprecise economic models and often very non-traditional... For example, the public demand ... goes beyond desire or need and is widely considered to be a right, not merely a privilege.”
- (3) Federal and state laws require providing health care services irrespective of the user’s ability to pay for such services.
- (4) Unlike many consumer products, health care is not readily capable of qualitative measurement. This is particularly true as service increases in complexity.
- (5) The isolation of the consumer from the economic consequences of purchasing health care in most instances is a clear departure from most free market economic models.
- (6) The increasing inability of providers to charge consumers for the proportionate total economic cost of providing care to the providers’ universe of patients presents significant problems. ... few classes of purchasers are willing to provide the resources necessary to care for those persons who are uninsured or otherwise unable to pay for needed health care services.
- (7) There is “... considerable discomfiture with a complete surrender to the market to determine who receives life saving treatments and who does not.”¹³⁸

Render argues that “[h]ealth care policy to date has often been based on anecdotal evidence, personal experiences, and often the relative influence of various interest groups”¹³⁹ but that “[e]mpirical data has not yet been a significant tool in driving public policy in those areas where legislators have considerable experience or deeply held convictions.” His apparent faith in empiricism is evidenced by his claim that “there is some promise that particularly ill conceived public policy may be modified by public education based on valid empirical data” and that “empirical evidence might still serve a major role in crafting necessary refinements in the current market based paradigm.”¹⁴⁰

XIV. Regulation, Deregulation, Regulation, Deregulation, Regulation.....

The National Health Planning and Resources Development Act of 1974 sought to rationalize the distribution of health services and give states a mechanism to make prospective determinations of need for new health care services. It has proved more problematic than originally envisioned. In the 29 years since, it has become almost completely a creature of state law, with some states repealing CON and others substituting stricter licensure instead. Some writers, such as Michael Flanagan, contend that CON requirements have failed to demonstrate a positive correlation between restricted market entry and lower costs per unit of service.¹⁴¹ Flanagan notes that Texas, Tennessee, California and Virginia removed CON application to home health agency development in recent years. Tennessee reinstated it, however, after rapid growth in HHAs “threatened to destabilize the entire industry”.¹⁴² Other states have imposed moratoria on issuance of new HHA CONs: Florida, Georgia, Alabama, Kentucky, and Mississippi. There is a significant difference, however, between the home health agency market and hospital markets, that being the prevalence of capitation as a payment source in home health. Medicaid and managed care plans dominate the payment models in HHAs and provide natural constraints on the growth of HHAs.¹⁴³

In 2001 CON critics in New Hampshire launched an effort to do away with CON, saying the Health Services Planning and Review Board “favors the state’s 28 hospitals over doctors, medical practices and other health care providers, preventing true competition in the state’s health care system.”¹⁴⁴ The board’s defenders pointed, however, to research indicating that health care is better because of regulation and that “while there is market concentration (of hospitals) there is not market abuse”¹⁴⁵ The study also found the allocation of health care resources in New Hampshire was well-distributed.

This debate illustrates another important aspect of the market failure and monopoly aspects to health care: to be a monopoly is not necessarily to act anti-competitively and in contravention of the public good. Health care economists Bruce Spitz and Boyd Gilman studied this issue in New Hampshire and concluded that although, particularly because of the rural nature of the state, the hospitals served discreet market areas and did not compete with one another, they did not abuse their monopoly status. They did not raise prices, for example, as much as they could have, but rather conducted themselves with much regard for the community good.

Mike Hill, president of the NH Hospital Association, noted this research. “If you look at the study you see that unlike perhaps Boston, where you could have eight hospitals in a mile, in New Hampshire you tend not to have that (density) except perhaps in Manchester or Nashua. You could argue that New Hampshire hospitals don’t have a lot of competition ... The study said that’s true but there was no evidence of misuse of that market situation. The issue is not monopoly. It’s abuse of monopoly power, and there is no evidence of that.”¹⁴⁶

Elizabeth Crory, Chairwoman of the CON board, advocated looking at eliminating the thresholds because of a lot of “gamesmanship” from health care developers who try to avoid a CON by “using creative ways of keeping the proposal under the threshold.”

“Some of the applicants have got quite clever in coming up with means of getting around the law,” the former Hanover state representative said, “such as leasing the equipment in order to lower the cost.”¹⁴⁷

The associate CON commissioner noted that “There is a certain amount of game-playing around what the project is and how much it will cost, and it leads to a lot of disputes.” Crory says “One conclusion of the state study of health care is we have good laws and our hospitals are not in the financial morass of many hospitals in other states...”¹⁴⁸

There have been many skirmishes in recent years over whether to retain or repeal CON. In 2002, Maine was the site of a heated debate about CON.¹⁴⁹ Those favoring repeal argued that new health care services are great, and competition creates better prices, higher quality and options for patients. Those favoring keeping CON replied that that supply will outweigh demand, providers will shift losses to other areas, and costs will go up for everybody with higher insurance premiums and reduced benefits resulting.

Again, a group of doctors was pitted against hospitals in this debate. The Maine Medical Association, representing doctors, favored repeal of CON, contending that managed care will control health care spending. The Maine Hospital Association disagreed, fearing that repeal would hurt hospitals via cream skinning. The Medical Association’s expert, Robert Hackey, professor of health policy and management at Providence College, contended that his research proves that the 14 states that abolished CON are not seeing higher healthcare costs than states that still have CON. Supporters of CON touted research showing better quality outcomes in places with higher volumes.¹⁵⁰

In Tennessee, Dennis Pettigrew, CEO of Erlanger (a Chattanooga health system) reported in 2001 that statistics showed that once services no longer are regulated there is rapid duplication of them. He agreed, however, that the process in Tennessee had gotten too political and needed to be run by a free-standing committee.¹⁵¹ Subsequently, Governor Don Sundquist signed a bill that “streamlines the certificate of need (CON) process for Tennessee’s health care industry” expressing his opinion the new system would “lead to faster and more solid decisions as well as an improved appeals process.” A major change in the program involved how CON considered projects’ potential effects on TennCare, Tennessee’s health care insurance program for low-income people. The reform legislation mandated that the effects on TennCare be taken into consideration with every CON application.

According to Rosie Pryor, Director, Marketing and Planning, McKenzie-Williamette Hospital, Springfield, Oregon, “...there is a backlash forming after 20 years of mergers, acquisitions and CON laws that failed to control rising costs.” She claims that “...all that did was eliminate competition for some and help create the mega-hospital systems now throwing their weight around in their respective markets.” Now, according to Pryor, these larger, more-expensive hospitals are pushing back against insurers “that seek to highlight comparative hospital costs through tiered network plans or simply by ranking facilities according to cost in plan member handbooks...”¹⁵²

In Georgia in recent years, the CON battles included two hospitals competing over the provision of cardiac care services, two other hospitals fighting over which would get to build the first hospital in a particular suburb of Atlanta, and still two other hospitals teaming up to oppose a third hospital's bid to open the first new cardiac unit in metropolitan Atlanta in almost 20 years.¹⁵³

CON was established in Georgia in 1982 and almost repealed in 1997. Republican Rep. Susan Cable (Macon) thinks it's about an uneven playing field. Tom Piper, director of Missouri's certificate of need program, argues, however, that "When two-thirds of the money that goes into health care comes from Medicaid, Medicare, etc., the public needs public oversight." Rep. Terry Coleman (D.), chair of the House Appropriations Committee sees it as a well intentioned program that now "in some places" is used "as protection" (of existing providers). He notes that it is intended to save costs but "there are no definitive national studies on whether such laws hold down the price of health care."¹⁵⁴ One of the most often heard arguments in Georgia in favor of the regulation is that it gives public hospitals an edge over those that don't treat as many indigents.

In North Carolina, in 2002, a request for a replacement of the 75 year-old, for-profit Eye and Ear hospital was rejected as not needed. The case provided an example of the modern CON debates about "cherry picking" and the line between public input and political influence in the CON process. County commissioners, the hospital corporation that owns Durham Regional, and the Duke University Health System all opposed it claiming it would add to yearly losses at nonprofit hospitals by facilitating cherry picking by the replacement facility. The applicant said was simply more costly to renovate the old facility than replace it. The applicant also claimed the cherry picking argument was not relevant because fully 45% of its patients were Medicare, Medicaid and charity cases. The facility also argued the case was about a patient's right to choose where to get care. The opponents claimed, however, that patients don't really make such choices, doctors do, and doctors have a financial interest in sending their patients to facilities they own.¹⁵⁵ Of course, this argument gives credence to the complaint that hospitals really compete for the allegiance of doctors, further illustrated by such things as hospitals' purchases of physician practices.

XV. Does CON Work?

James Blumstein and Frank Sloan (1978) considered some of the early analyses of the effectiveness of CON programs. First, however, they noted the significant problems inherent in trying to evaluate the effectiveness of CON:

- lags between project conception and when the doors open
- significant amounts of "grandfathering" of facilities and programs
- states facing unusually high rates of hospital cost inflation might be among the first to adopt CON. If so, estimates of the effects will be "biased unless special statistical techniques are employed."¹⁵⁶

- interactions between CON and other regulations such as rate control and section 1122. How can one tell which, if any, is responsible for a perceived change?
- effectiveness may be highly dependent on the political environment and receptiveness to regulation.

They also noted that, when evaluating, it is necessary to consider unintended consequences. For example, have CON regulations resulted in expensive equipment, such as CT scanners, moving from hospitals to doctors' offices in order to avoid review?¹⁵⁷

According to Blumstein and Sloan, a "common analytical approach is to review certificate-of-need applications over a given period and monitor the percentage of applications disapproved and the amounts of capital expenditure avoided. " But this does not account for projects that might have been initiated in the absence of CON but which weren't filed because of anticipated rejection, what one might call the sentinel effect. Also, this evaluation technique can't measure shifts in investment from regulated projects to unregulated projects.¹⁵⁸ These early studies of CON included the following:

Lewin and Associates did research assessing the impact of CON in several states. They found that:

- because of costs involved and damage to the relationship with the regulatory agency, hospital administrators did not want to pursue projects that were likely to be rejected
- CON resulted in increased planning and coordination among hospitals, including development of shared services and joint medical programs
- CON accelerated timetables for facilities construction and introduction of special services
- there was a belief that reviewers favored existing providers to the detriment of new entrants¹⁵⁹

The Macro research company did a study and concluded that:

- hospital associations have been among the most active CON supporters
- funding for the CON programs appeared to be inadequate
- criteria to determine need are weak and poorly developed¹⁶⁰

Studies by Salkever and Rice, and by Hellinger revealed that:

- CON reduced bed expansion but increased expansion in plant assets per bed, the resulting impact being nil¹⁶¹
- (Hellinger) concluded CON did not significantly reduce hospital investment – caution, however, that he did his research at a time when hospitals were believed to be accelerating investment to get it in under the wire before CON laws took effect in their states

Research by Sloan and Steinwald, and by Policy Analysis-Urban Systems Research and Engineering found few meaningful differences between CON and non-CON states.¹⁶²

XVI. More Does it work? The Best Made Plans – and Loopholes -- of Mice and Men

At the University of North Carolina, a project was proposed to link two hospitals. The cost was pegged at \$143 million but omitted interest costs of \$15 million. In 2001 the project was \$26.6 over budget and 95% built. What use would there be in going through a process to apply for and receive a corrected or amended CON? If, on the other hand, that process is not required, what incentive would there be for any future applicant to correctly state the price and parameters of its proposed project? In this case, the hospital's senior vice president for operations' comments about the fit and finish of the new construction likely turned heads at the regulators' offices. He was quoted as saying:

“With features, such as intricately designed terrazzo flooring in the lobbies, and two-floor, glass-encased concourse, the new facilities will be a step up from most medical facilities.¹⁶³ ...It's beyond being construction. It's being sculpted. It's almost like a work of art. It's unlike anything we've ever had... We want the physical environment as beautiful and cheerful as possible.”¹⁶⁴

In West Virginia, regulators wonder about CON effectiveness because 98% of the applications submitted between January of 1996 and June of 2000 were approved.¹⁶⁵ In 2002, massive hospital expansion plans were in the works (\$443 million approved) but the hospitals' financial condition was weak, according to Sonia Chambers, Health Care Authority chairwoman: “One of our biggest concerns is, if they are that financially fragile, how are they going to afford these large capital expenditures?” The authority also regulates hospital rates. Two hospitals, six miles apart, each wanted to do major building programs (\$265.2 million, 318 bed replacement hospital and a \$75 million, 199 bed replacement hospital). Thirty five miles away, another hospital wanted to do a \$74.5 million, 51 bed expansion of its 380 bed hospital. The state was considering denying both requests (in the 6 mile case) unless they worked together on one proposal.¹⁶⁶

In Florida, where batching of CON applications is prevalent, unintended and negative consequences of batching have appeared. Consider the case of Martin Memorial Hospital in Stuart, Florida. It received a CON for open-heart surgery, but a competitor appealed. Lawnwood Regional Medical Center (down the road in Ft. Pierce) said the open-heart surgery program was not needed at Martin. Lawnwood had the only regional complete heart center.¹⁶⁷ As the appeal would surely last beyond the next batching cycle and Martin risked losing the appeal, Martin applied again in the next batching cycle while waiting for the appeal to be resolved. Bruce Middlebrooks, of the Agency for Health Care Administration, says this redundancy is common practice.

According to Ralph Gladfelter, senior vice president for the Florida Hospital Association, “Dueling hospitals fighting for the right to provide money-making treatments might seem a case-study in the complications of American medical care, but state officials say the situation is common – and necessary. Quality control often goes hand in hand with

control of the market, said state officials and others familiar with the procedure.” Gladfelter claims that there is “an unmistakable connection that exists between a program with high volumes and better outcomes.”¹⁶⁸

Larry Horwitz, president of the Economic Alliance for Michigan, argues that “quality is enhanced when fewer physicians and institutions perform such difficult procedures as heart-bypass surgeries.”¹⁶⁹

Also in Florida, hospital lobbyists opposed a bill in 2000 to end CON because they claimed it would threaten patient safety and the “economic vitality of hospitals that treat a high number of poor and uninsured patients. “ The Florida Hospital Association (200 members) said CON was needed to prevent overexpansion that erodes care quality.

Gladfelter cited a study by the University of Iowa indicating that mortality rates are 21 percent lower in states with certificate of need programs compared with states that do not have them. For open-heart surgery that means nine preventable deaths per one thousand procedures.¹⁷⁰ The Florida Hospital Association claimed that “quality control often goes hand in hand with control of the market” and that there is “an unmistakable connection that exists between a program with high volumes and better outcomes.”¹⁷¹

A study in the Journal of the American Medical Association “identified 11 medical procedures and conditions in which volume was critical. At hospitals doing fewer than 30 abdominal aorta repairs, for example, patients were 64% more likely to die than at busier facilities.”¹⁷² Susan L. Meyers reported “While there have been no significant studies of how abolishing the health planning regulation affects health care costs, research shows that having too many specialty units in a market can affect patient safety.”

Tom Piper, the head of the Missouri CON program, and a leader of the American Health Planning Association, continues to maintain that CON laws work. Piper states that through tracking planning and CON programs for the past 13 years through the AHPA, administering the Missouri CON program for almost 18 years, having studied health planning and CON in many states and hosted numerous local and national debates on the topic many times, he knows CON works. Piper claims that the anti-CON forces “have told only part of the story” leading to the wrong conclusions.

According to Piper, “CON and other community health-planning efforts do work and desperately are needed.” He cites, for instance, the state of Tennessee which he notes discarded its old CON program but then had to reinstate one to rectify very rapid facility growth. He also notes that CON programs vary from state to state and although someone might be able to point to one example in one state where the cost seemed too high and the benefits too low, other states have cost-effective and valuable programs.¹⁷³

The calls for revisions to CON law are also not all in the direction of weakening or doing away with CON. In North Carolina, for instance, Blue Cross Blue Shield sought a lowering of the jurisdictional threshold from \$2 million to \$750,000 because manufacturers were cutting deals with hospitals to get in under the wire. That reform

legislation also extended jurisdiction to doctors who set up free-standing laboratories and radiology centers because they have “lower overhead costs ...often skim off a neighboring hospital’s profitable programs...”

Duke University’s Duncan Yaggy notes a less visible but perhaps more valuable benefit to CON, improved planning that happens at the facility level. Yaggy claims “[i]t’s an important exercise because it really compels you to be sure that what you are doing is sensible, that it passes the red face test.” It can also provide hospital executives “with a convenient excuse for not expanding,” he said.¹⁷⁴

A common CON battleground nowadays pits existing, full service hospitals against proposed specialty hospitals that the existing hospitals fear will steal the few profitable cases from among the existing hospital’s book of business. In the “tri-cities” area (Johnson City, Kingsport and Bristol) of Tennessee, for instance, Wellmont Health System planned to create a “boutique hospital” with a group of physicians. Wellmont owned all the hospitals in Bristol. The plan was vigorously opposed by those arguing that the area had excess bed capacity.¹⁷⁵

XVII. CON as Implementation Gone Awry

CON programs are characterized by numerous flaws that limit, or at least seriously challenge, their effectiveness. Among these are:

- Grandfather clauses exempting institutions and programs pre-dating the laws.
- Loopholes such as allowing hospitals to avoid CON by leasing instead of purchasing equipment.
- A lack of competing applications, usually resulting in a completely one-sided hearing with only the applicant addressing the issues.
- Political pressures, especially because most CON decision-making bodies don’t have rules against ex parte communications
- Difficulty of defining need, resulting in (1) a dependence on physicians’ definitions of need and (2) confusing demand for need
- Difficulty evaluating new technologies, especially in early years
- Ruling bodies lacking incentives to turn down applications:
 - Local political pressure favors projects
 - Costs are spread across the system¹⁷⁶
- Exemptions:
 - For example, in California the law exempted remodeling and replacement of machines. This resulted in \$250 million of such spending in just the first year of the exemption.¹⁷⁷
 - The “physician office” exemption that was intended to exempt the traditional, freestanding, independent doctor’s office from CON regulation but also allows large hospital-owned physician practices to escape review.
- Providers have an incentive to push up their plans and be the first one to apply (except where applications are batched).¹⁷⁸
- The laws are often ambiguous, as was the 1974 Act, about what level of

- government is to define need.¹⁷⁹
- Sanctions are often lacking,¹⁸⁰ ill-defined, inadequate, or counterproductive (the most common sanction, a fine on the facility, winds up increasing health care costs and being paid from by consumers and third party payers)
- The 1974 Act did not require states to assert authority to reduce or eliminate facilities or services.¹⁸¹ State CON laws focus almost exclusively on newly proposed facilities and programs.

Perhaps more important is that CON only addresses one part of the hospital cost pie. It does not limit non-capital expenses, the number of units of service provided, prices charged, staffing ratios, salaries, supplies and non-capital equipment, equipment below the thresholds, or utilization – the number of admissions, length of stay, procedures done, etc.¹⁸² Even if CON is able to squeeze health care costs in one area such as construction of facilities, some argue that it merely acts like pressure applied to a balloon – it pushes down expenses in one place but lets them pop out elsewhere.

Currently, Maine, Kansas, Maryland, and Minnesota are engaged in collecting data from a broader source, namely insurance claims data. Vermont's legislature has called for the state to implement a multi-payer claims based database. Through such data collection, almost all of a state's health care utilization could be analyzed, including hospital visits, doctors' visits, pharmacy expenditures, and even some alternative care expenditures.

Notably, evidence does not exist indicating deregulation is effective at slowing health care cost increases. From 1981 to 1991, a period of a significant push toward deregulation, there was a \$448 billion rise in health care costs, rising twice as fast as the consumer price index. During that ten-year period, health care spending rose from \$290 billion to \$738 billion. Some believe de-regulation failed. It certainly faced the same market challenges regulation has, including the significant fact that the market is not free because of third party payment. Business coalitions pushed for re-regulation as a way to hold down costs for their members. Forces such as the Atlantic Health Care Alliance, composed of Coca-Cola, Delta Air Lines and BellSouth, argued for re-regulation.¹⁸³ Georgia and Virginia responded to the pressures by expanding CON jurisdiction. In Georgia, the equipment threshold now applies to doctors' offices and free-standing clinics as well.

XVIII. Strange Bedfellows: Pro-CON parties and rationale

We now see three significant forces in support of CON laws: regulators, existing hospitals and employers - particularly large, well-organized employers. Regulators appear to continue to have some faith that CON works or at least is better than not having CON. Existing hospitals seem clearly to desire the protective nature of CON, keeping new competitors at bay. Some employers see CON as helping keep their health care insurance costs down - or at least keeping the rate of increase from being worse.

Some hospitals and corporations think CON is a "critical brake against a costly proliferation of medical construction that would be unleashed on health care consumers"

without it. With health care inflation soaring, many lawmakers are now looking to “re-regulate or strengthen existing rules,” the Wall Street Journal reports.¹⁸⁴

Citing a projected \$280 million Medicaid deficit for FY 2002, Kentucky Governor Paul Patton (D) imposed a “moratorium” on an array of new health projects and services, exempting projects for acute care beds, neonatal units, organ transplant programs, cardiac catheterization services or projects that already had had a public hearing.¹⁸⁵

In Ohio in 1995, the Department of Health estimated there were 297 excess rehabilitation beds. Within a few years, another 365 beds had been added. Although some process is still required before building a new hospital, ambulatory surgery centers were deregulated in 1996 and in one year “56 operators announced new ambulatory surgery centers in cities.” Gretchen McBeath, a Columbus Healthcare attorney, says they “suck revenues from rural hospitals” and could lead to higher charges.

The American Health Planning Association reports that between Ohio’s repeal of CON in 1995 and the year 2002 the following unregulated activity occurred:

- ◆ The addition of 133 new ambulatory surgery facilities
- ◆ 26 new hospitals
- ◆ A 38% increase in open heart surgery
- ◆ The addition of 82 new MRI or CT scanners
- ◆ 567 new psychiatric beds
- ◆ 8 new transplant services
- ◆ 14 new lithotripters
- ◆ 20 new obstetrical services
- ◆ A 41% increase in rehabilitation beds
- ◆ 337 new med/surg beds
- ◆ 13 new radiation therapy services
- ◆ 1100 new heliodialysis stations

Some employers are joining the pro-CON side because they see hospital expansions and proliferation of high-end equipment as a big source of soaring premiums. In Michigan, auto makers and the United Auto Workers union have lobbied to block a CON repeal effort. Daimler Chrysler testified in March 2002 that its health care spending totaled \$3,519 per employee or family member in Wisconsin and \$2,741 in Indiana, two non-CON states, and \$1,839 in Michigan and \$1,331 in New York, two CON states. (Wisconsin is 91% higher than Michigan, 164% higher than New York, Indiana is 49% higher than Michigan and 106% higher than New York).

Over 150 Michigan hospitals, businesses, and labor unions are on record as favoring CON “as a check against the proliferation of medical services”¹⁸⁶ and a means to enhance quality.¹⁸⁷ Ford Motor Company released a study in February of 2002 showing it pays 12-39% more for certain patient services in Ohio and Indiana, which have repealed CON, than in Michigan and Kentucky, where CON still exists. “The data clearly favors states

with certificate of need,” said Toshiki Masaki, a Ford policy manager in government affairs.¹⁸⁸ One health care economist who reviewed this study and a similar one by Chrysler found numerous, fundamental problems with the research methodology, however, such as failing to account for cost differences in the states studied that are completely independent of CON’s presence. Also, it appears the studies did not account for differences in health care costs based on local factors such as whether the factory was in a large city with a high cost health care system not attributable to CON or lack of CON.

Some states ended CON “on the theory that reimbursement rather than regulations would dictate the pace of medical expansion.” The theory is rock solid but there is a huge hole in the reimbursement dike and that hole is the cost shifting that hospitals can and do engage in. Rather than see the Medicare reimbursement cap as something that forces a slowing of the growth of facilities and equipment, hospitals charge higher prices to privately insured and self-paying patients to make up for what they are not receiving from Medicare.¹⁸⁹

Many doctors are now pushing for the elimination of CON but hospitals are pushing to keep it. Recent years have seen big battles over the provision of open-heart surgery and cardiac catheterization. Mary Mayhew, with the Maine Health Association, says if private pay patients go to a physician-sponsored service instead of the hospital, prices will inevitably rise at the hospital. This is based on the theory that the hospital has few ways to cut costs and must therefore raise prices on the services only it provides in order to make up for the loss of business. Whereas the hospital has to maintain cost centers, such as the emergency room, that lose money but are needed by the community, the FASC can build only the infrastructure needed to perform the profitable procedures it wants to perform. Some jurisdictions with CON have dealt with this conundrum that, in part, concerns the hospital’s provision of free care, by requiring FASCs to provide a prescribed amount of free care as a condition of CON approval. Mayhew also claims that if the number of places offering services increases, the use of those services will also increase, thereby driving up costs (the Roemer Effect).¹⁹⁰

Health care economists says spending on new buildings and equipment generates additional spending in later years as hospitals and clinics hire employees and perform additional procedures. Former Colorado Governor Roy Romer regrets suspending the CON program in 1987: “I think it was a mistake. We’ve seen an explosion of costly and duplicative services since then.” Kentucky Governor Brereton C. Jones imposed a 1-year ban on major new spending by hospitals, clinics and nursing homes so the state could come up with a plan.

Between 1989, when Virginia abolished review of equipment such as M.R.I. machines, and 1992, the number of M.R.I. machines doubled to 58, and other equipment spending rose rapidly. David G. Brickley, a member of the Virginia House of Delegates proclaimed that “Our premise in 1989 was that health care was based on supply and demand. If there were more M.R.I. and C.A.T. scanners available, the price would go down. What happened was just the opposite. More machines are available, they’re not

being fully used and costs are higher than ever.” In Wisconsin, Governor Tommy Thompson reinstated CON in 1992 after repealing it in 1987.¹⁹¹

State budget crises have also lead to renewed support for CON with some legislators considering controlling inpatient hospital rates, pre-approving new construction projects and permanently banning hospital construction and renovation.¹⁹²

XIX. Anti-CON Parties and Rationale

Critics point to how counterproductive and unintended some of the consequences and processes have been in CON battles. For instance, in a contest between a for-profit hospital corporation that wanted to build a 220 bed hospital and a non-profit that wanted to expand, a huge public relations battle was waged to influence the CON agency. The CEO of Legacy Health Systems, the for-profit company, went so far as to publicly proclaim, in a bid for public opinion, “I’ve got \$200 million that I’m willing to bring into the community. Can you use it? We need your vote. This is going to be, in part, a weighing of the letters. How many for, how many against?”¹⁹³

In an anti-CON editorial in *Modern Healthcare* in 2002, David Burda complained that “As the nation’s purchasers of healthcare services look for ways to control their escalating healthcare costs, health planning through the certificate of need process is getting renewed attention.” Writing in reaction to the Wellmont Health Systems controversy in Tennessee, he complained that consumers “stand a better chance of lowering their healthcare bills with wide-open competition among providers for facilities and services.” In particular, his complaints seemed to deal with a perceived unfairness in how CON is run.¹⁹⁴ Burda contended that CON outcomes “depend on which lawmakers or administrators you know, how much money you have, how persuasive your lawyers are, how creative your consultants are, how much time you have and whether you are willing to compromise.”

According to Tom Piper, ED of Missouri’s CON program, one “leading argument” for decreasing CON is that “market-driven managed care, with its emphasis on lower utilization, will supplant the regulatory apparatus...The competitive framework will winnow the best candidates for [the] new infrastructure.”¹⁹⁵

The Columbia/HCA hospital group sees CON as a “major barrier” to entering a new market. It fought hard for removal of CON in the state of Georgia, lobbying in particular for removal of CON for approval of heart surgery and obstetrics and for removal of requirements that mandate 3% of patient load be indigent care.

With the benefit of hindsight we now know that managed care largely failed at the cost control effort because (1) it seriously underpriced its products in the 1990s to grab market share and counter the Clinton health care reform plan, and (2) was outmaneuvered by health care providers, mostly hospitals, that increased monopoly power through mergers and succeeded in characterizing the insurance companies as greedy, uncaring, faceless corporations working to deny sick people the care they needed. As the public demanded

significant insurance market reforms such as coverage mandates, extensive appeal rights and less restrictive provider networks, managed care plans lost what marginally improved abilities they had to contain costs.

XX. Everybody wants to be a Heart Surgeon

Perhaps the dominate modern CON battleground is in the field of heart surgery. Reviewing the CON literature from the past several years produces an overwhelming concentration of cases concerning hospitals wanting to get into the heart surgery business and others opposing their efforts. The familiar issues are argued vigorously: care quality, cherry picking of profitable lines of service, weakening of existing facilities that are providing the services, and increasing overall system costs through duplication, excess investment and the behavior of covering stranded costs by hiking prices on other services.

In Philadelphia, Abington Memorial Hospital tried unsuccessfully three times in nine years to get approval for open-heart surgery. There already were several nationally renowned heart centers in Philadelphia. Within twenty-four hours of Pennsylvania's CON law lapsing, however, Abington opened an open-heart surgery program. It's vice president for management services noted:

“There's something of a halo effect with open-heart. The public assumes once you do open-heart surgery, you are in the big leagues in tertiary care. I also think it made a big difference in the confidence of the hospital.”¹⁹⁶

Will the competition work out in the end and produce a more efficient marketplace for heart surgery in Philadelphia? It may prove to be a good case study. Many argue that there are too many hospitals in the area: “The distinguishing feature (of the market) was and remains that there are only several dominant insurers and too many providers” Leon Malmud, M.D. and president and CEO of seven-hospital Temple University Health System said. He claimed that, in order to gain market share, health systems began buying physician practices and that launched a “feeding frenzy” with hospitals moving defensively so they “wouldn't be left out in the cold.” According to Steven Altschuler, M.D. President and CEO of Children's Hospital of Philadelphia, “It was arrogance and stupidity – it still irritates me to no end.”¹⁹⁷

The buying spree ran up everyone's debt, from which most are still recovering. In 1998, the Allegheny Health, Education and Research Foundation went bankrupt, threatening to take down eight Philadelphia area hospitals and a medical school. The for-profit Tenet Healthcare system entered the market, closed one hospital and is nursing the others back to health.¹⁹⁸

Pro-regulation advocates might see these events as proof of the failure of de-regulation. Pro-competition advocates would likely argue, however, that the market is working competitively to correct a system characterized by oversupply and high costs and charges. Pro-regulation folks might further respond that, even if this shows a logical competition-based reaction to oversupply, it strengthens rather than weakens the

argument for CON in rural and other areas with few hospitals and where CON is seen as serving the goal of maintaining access to health care in a market that cannot do so through the usual market forces. To which pro-competition proponents might further respond that CON can go too far, not only preventing competing hospitals from entering the market – something that might be unlikely in a rural setting in any event – but by also raising obstacles to other forms of competition, such as freestanding ambulatory surgery facilities, that might want to enter such markets.

Heated conflicts about the provision of heart surgery have also been flaring in Maryland, where, after a two-year study of CON (1999-2001) mandated by the Maryland legislature, the conclusion was to keep CON.¹⁹⁹ The CON program in Maryland is restricting which hospitals can do open-heart surgery (five in the Baltimore area) and others have gone to the legislature for relief. Given that the leading argument against CON has been that it doesn't work to cut costs, their argument is quite remarkable: they claim CON should be done away with because it has served its purpose of lowering health care costs. They advocate a new approach, licensing for quality control rather than regulation for supply control.²⁰⁰

St. Agnes HealthCare is one of the Maryland hospitals that wants to do open-heart surgery. Dr. Steven Plantholt, Chief of Cardiology, says they transfer 200 patients a year to other hospitals for heart surgery: "When you look at what is the leading cause of death and illness in our society, it's cardiac disease. Yet, you can do brain surgery at any hospital." The Maryland Health Care Commission has rejected two applications from St. Agnes for a CON so the hospital has sought help from the legislature. The Commission says more cardiac surgical centers are unnecessary. Pam Barclay, deputy director of the MHCC claims "We regulate several different specialized health care services, including cardiac surgery and obstetrics, because they are highly specialized and because of the relationship of volume and quality."

The volume of cardiac surgery in Maryland is relatively stable and there are enough providers. If it became a licensing system, fourteen hospitals would be added to the nine that currently perform heart surgery, resulting in \$28-\$42 million in capital costs. Also, some argue that quality would suffer. Dr. Henry Meilman, chief of the cardiac catheterization lab at Union Memorial Hospital says that: "In California, with a proliferation of heart surgical programs, the chance of dying is twice what it is in Maryland....Any heart program should be doing 800 cases, maybe even 1000 per year. ...If you look at California, an average program is doing 90 cases...The medical literature is clear that a higher volume of cases produces better outcome." Plantholt disagrees, however, arguing that "If volume is the only indicator of quality, then what you are saying is McDonald's is a five-star restaurant."²⁰¹

In Florida, Martin Memorial Hospital received a CON for open-heart surgery, but a competitor appealed, so Martin applied again in the next batching cycle while waiting for the appeal to be resolved. This extra regulatory process happens often in Florida as a safeguard against losing an appeal says Bruce Middlebrooks of the Agency for Health Care Administration. One of Martin Memorial's competitors, Lawnwood Regional

Medical Center (it has the region's only heart surgery program) says the surgery unit is not needed at Martin:

“Dueling hospitals fighting for the right to provide money-making treatments might seem a case-study in the complications of American medical care, but state officials say the situation is common – and necessary. Quality control often goes hand in hand with control of the market, said state officials and others familiar with the procedure.”²⁰²

Ralph Gladfelter, senior VP for the Florida Hospital Association, claims “There is an unmistakable connection that exists between a program with high volumes and better outcomes.” The state of Florida has prescribed a threshold of 350 open-heart cases a year as a standard for adequate volume.²⁰³

Opponents of the threshold claim that open-heart surgery has become “increasingly routine” and some have sought legislative help to overcome the regulations. While CON backers cite improved quality by limiting access, critics counter that the regulatory process is litigious, laborious and expensive. They claim that market forces and regulation of program quality would be more effective. Under a bill sponsored by one legislator, Indian River Memorial Hospital, a hospital seeking to start a heart surgery program, would “be given special consideration to provide open-heart surgery and angioplasty.” That proposal is framed as furthering increased access in the five Florida counties that don't have such programs. Another bill exempts all open-heart surgery programs from CON. Such bills enjoy some success in the Florida legislature. For instance, by a 7-4 vote the House Health Regulation Committee approved – over the objections of the Florida Hospital Association - the bill to exempt all open-heart surgery programs from CON. FHA Vice President Gladfelter admits, however, that he has “known certificates of need that have cost more than \$1 million,” and that “It is a very expensive process, particularly in the case of open-heart surgery,”²⁰⁴

XXI. Case Study #4: Greed, Lies and Kickbacks in Naperville, Illinois?

In 1998, the Health Facilities Planning Board in Illinois put an emergency rule in place mandating in-depth reviews of proposed hospital sales. Concerned about “aggressive acquisition tactics employed by for-profit chains such as Columbia/HCA Healthcare Corp.” the goal was to ensure public scrutiny and comment before sales. Columbia has eight hospitals on the market in the Chicago region at the time.²⁰⁵ Other changes in the hospital landscape were also bubbling up in this time frame in Illinois. In 1999 CON regulation became a very controversial topic in Illinois as a coalition of entities led by Edward Hospital (in Naperville, 30 miles west of Chicago) submitted a CON application to construct a for-profit five-story “specialty” cardiac care hospital to be called, simply, Heart Hospital. The price tag was set at a very precise \$92,391,587. It was to be built adjacent to Edward Hospital, an existing hospital with 56 medical/surgery beds, 15 ICU (intensive care unit) beds, 2 operating rooms, 3 cardiac catheterization labs, and cardiac diagnostic and rehab departments.²⁰⁶

CON in Illinois is administered by the Illinois Health Facilities Planning Board, consisting of 15 members appointed by the Governor for three year terms. The membership is prescribed in statute as follows:

- 8 consumers, 1 representative from commercial health insurers, 1 representative from proprietary hospitals, 1 person active in hospital management, 1 registered nurse, 1 physician in active private practice, 1 representative from a skilled nursing or intermediate care facility, and 1 from ambulatory surgery care management.

Key criteria that applicants must meet include proving the project is needed and is the most effective and least costly alternative.²⁰⁷ Hearings must be held within 90 days of application, and a hearing officer conducts the hearings. The parties have the right to give testimony, produce evidence, cross-examine adverse witnesses, and present argument.²⁰⁸ Failure to get a CON from the Board, or noncompliance with CON, can result in penalties, fines, sanctions, or revocation of the CON.²⁰⁹

Heart Hospital was not proposed as a new hospital, but rather as a modernization of an existing hospital. Linden Oaks Hospital, a psychiatric hospital owned by Edward Hospital and located about half a mile away was licensed for 110 beds. The proposal indicated that Heart Hospital, although not a psychiatric hospital, would assume Linden's license.²¹⁰ About half of the psychiatric beds were to be transferred to Edward Hospital and the other half substituted with heart surgery beds in the Heart Hospital.

The contest was extraordinary, with over 300 people attending the first hearing on August 24, 1999. The opposition consisted of a group of seven charitable, not-for-profit hospitals from three Chicago area counties, calling itself "The Alliance for Governmental Action." All were allowed by the rules to participate as intervenors. They presented four complaints:

1. The proposal violated CON rules;
2. There was potential misuse of charitable assets;
3. There were fraud, abuse and physician self-referral concerns; and
4. There were threats to health planning and the orderly delivery of health care.²¹¹

The Heart Hospital investors claimed that their longstanding commitments to the Alliance hospitals would not change if the Heart Hospital got approved but that they felt "that the Heart Hospital proposal is an idea that is right for our time. It's right for our patients. And in particular, it's right for the Community of Naperville, given the demographics..."²¹²

The State Planning Board staff reviews CON proposals for compliance with criteria and issues a report. The SAR found the Heart Hospital proposal did not meet certain criteria:

- basis for discontinuation of mental health services at Linden Oaks

- establishment of mental health services at Edward Hospital
- an unmet community need for cardiac services
- an unmet community need for beds
- economic feasibility

The staff review used past and current cardiac services at Linden Oaks to measure the potential need for cardiac services there and found the Heart Hospital could not meet the threshold test for performing enough procedures (200 open heart procedures during second year of operation and 750 cardiac catheterizations performed in the past 12 months). Also, Edward Hospital did not address the addition of beds that would result. Furthermore, the applicant did not document that the volume of any existing service within 90 minutes travel time would not be reduced below 350 procedures annually for adults and 75 procedures for pediatrics (a state standard addressing lost utilization at existing facilities). The state report also concluded that the applicant had not addressed the issue of unnecessary duplication of services.

A second public hearing was held on January 13th 2000 and the Heart Hospital responded more to its opponents. It stressed the relationship of Heart Hospital to the corporate entity, Edward Health Ventures, and said the Board didn't need to look at the discontinuation (of current services) and establishment (of new services) criteria. Rather, it claimed the Board should just look at the entire EHV as the entity performing the project.²¹³ The applicant forecasted 88% growth in procedures between 1998 and 2004 and said it wouldn't "cannibalize other programs."²¹⁴

Of eight affirmative votes needed for approval, the project only received three, resulting in an Intent-to-Deny being issued. That gave the hospital notice and another opportunity to appear before the Board.²¹⁵ On March 13th, 2000, while continuing to defend its original plan, Edward Hospital submitted a new plan that reduced the project scale by about twenty percent, reduced the price to around \$70 million, and removed the purchase price of Linden Oaks from the proposal. At a subsequent hearing, on June 1st, 2000, the proposal received five affirmative votes,²¹⁶ still not enough for approval. The Heart Hospital proponents could have appealed but did not. The standard on appellate review in Illinois for such cases is whether the decision is against the manifest weight of the evidence or arbitrary or capricious. Thus, very few such cases succeed on appeal.²¹⁷

Some believe the State Planning Board in Illinois is very powerful, too political and lacking in effective accountability because it cannot be overruled by a state agency or hearing officers. One critic contends that "obtaining a CON has become an enterprise in itself ... 'becom[ing] so lucrative that it attract[s] many politicians and former politicians who successfully [use] their influence to weight the process for those who [employ] their services.'" ²¹⁸

Loyola University Medical Center, one of the Alliance hospitals, had former Illinois Republican Governor James Thompson lobby the State Planning Board and Edward Hospital hired former Illinois House Republican Leader Sam Vinson to assist its cause.

It is reported that at least 6 of the 15 Board members had been there 10 years or more and the chair, Pam Taylor, had been there over 20 years. There were generalized complaints that almost all projects were denied and expensive consultants were needed to complete an application.²¹⁹ Statistics by the State Planning Agency showed, however, that 88% of applications were approved upon initial consideration and 96% were eventually approved.

A Fiscal Report for the year 1998 brags that the State Planning Board has disallowed nearly \$1 billion in proposed capital expenditures since FY 1992 and saved billions in current and future dollars on behalf of health care consumers.²²⁰ The Fiscal Report contends that “states which have abolished CON programs experienced substantial development or expansion of facilities and services with no assurance or evidence that cost containment, quality of care, and access to services has been maintained.”²²¹

Legislative controversy followed the Heart Hospital case. In April of 2000, Governor George Ryan signed a bill which significantly amended the CON law, raising thresholds and limiting board members’ terms.²²²

XXII. In Closing

There is consensus that there is a cost crisis in health care. There is nothing approaching consensus, however, on whether to address it through a regulatory approach, a competition approach, or some other method.

The current structure of the health care system, the public good aspect of its purposes, and the need to assure quality make it impossible to have a completely unregulated system. If CON is to be used as a cost containment tool, however, its limitations must be acknowledged and it must be designed in such a way as to maximize its costs and benefits.

¹ Wing, Kenneth R., 36 Case Western Reserve Law Review 605, 1985-86, *American Health Policy in the 1980's*, pp. 608-609

² Inside the Industry – Devices & Drugs: Boom Ups Costs, Need for Oversight, American Health Line, June 14, 1999

³ According to Susan Bartlett Foote, author of *Managing the Medical Arms Race: Innovation and Public Policy in the Medical Device Industry*, per capita health care spending reached \$3,781 in 1996, up dramatically from \$141 per person in 1960.

⁴ Chayet & Sonnenreich, P.C., February 1978, Medicine in the Public Interest, Inc., *Certificate of Need: An Expanding Regulatory Concept – A Compilation and Analysis of Federal and State Laws and Procedures*, p. v.

⁵ Chayet & Sonnenreich, p. v.

⁶ Hammer, Douglas J., p. 75

⁷ Hammer, Douglas J., p. 75

⁸ Chayet & Sonnenreich, p. v.

⁹ Chayet & Sonnenreich, p. v.

¹⁰ Chayet & Sonnenreich, P.C., p. 1.

¹¹ Key, Charles M. , Esq., Tennessee’s 2002 CON Reform Brings Few Substantive Changes

¹² Charles M. Key

¹³ Chayet & Sonnenreich, p. vi.

- ¹⁴ Chayet & Sonnenreich, p. vii-viii.
¹⁵ Chayet & Sonnenreich, p. viii.
¹⁶ Chayet & Sonnenreich, P.C, p. ix
¹⁷ Havighurst, Clark G., 59 Virginia Law Review 1143 (1973), *Regulation of Health Facilities and Services by Certificate of Need*, p. 1143. Chayet and Sonnenreich reported in 1978 that “the chief manifestation of regulatory cost-control techniques has been a pronounced trend toward the enactment of so-called ‘certificate-of-need’ laws in the states.” It focused on regulating entry into the health services industry and on new investments in facilities, and used, as its primary tool, a requirement for a prior administrative determination of a public need for facilities or services.
¹⁸ Chayet & Sonnenreich, P.C, p. 3.
¹⁹ Havighurst, Clark G., p. 1144-7
²⁰ See, e.g. Kessler, The Hospital Business, Washington Post, Oct. 29-Nov. 3, 1972.
²¹ Havighurst, Clark G., p. 1149-50, footnote 23
²² Havighurst, Clark G., p. 1150, footnote 23
²³ Havighurst, Clark G., p. 1149-50
²⁴ Bovbjerg, Randall, p. 111, also Newsweek, May 8, 1978, at 43
²⁵ <http://www.t-c-m-s.com/history/George%20Kamp-Oral%20Roberts%20University.htm>
²⁶ <http://www.allevperts.com/previousqv.asp?QuestionID=1609293>
²⁷ http://www.publiceye.org/research/Group_Watch/Entries-105.htm
²⁸ Bovbjerg, Randall, p. 112-123
²⁹ Bovbjerg, Randall, p. 114
³⁰ Bovbjerg, Randall, p. 114-115
³¹ Bovbjerg, Randall, p. 115
³² Bovbjerg, Randall, p. 116
³³ Bovbjerg, Randall, p. 116
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